2013-1451

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

MEDISIM LTD.,

Plaintiff-Appellant,

v.

BESTMED, LLC,

Defendant-Appellee.

Appeal from the United States District Court for the Southern District of New York in Case No. 10-CV-2463, Judge Shira A. Scheindlin

PRINCIPAL BRIEF OF PLAINTIFF-APPELLANT MEDISIM LTD.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MEDISIM LTD. V. BESTMED, LLC, 2013-1451

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, Counsel for the Appellant Medisim LTD. certifies the following:

1. The full name of every party or amicus represented by me is: Medisim LTD.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: N/A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are: McCarter & English, LLP: Scott S. Christie, Keith J. McWha, Gerald Levy, Mark H. Anania, Matthew Sklar, Elina Slavin; Day Pitney, L.L.P.: Richard H. Brown, III, Elizabeth A. Alquist.

Dated: October 15, 2013

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STATEMENT OF RELATED CASES

Other than the current appeal, there has been no other appeal in or from the civil action in the lower court before this or any other appellate court. There are no other related cases pending in this Court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

Before the District Court, Plaintiff-Appellant Medisim LTD. ("Medisim") brought a patent infringement claim, a copyright infringement claim, Lanham Act claims, and claims arising under New York state law (including unjust enrichment, among others). The District Court had subject-matter jurisdiction over Medisim's claims under 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338 & 1367 because the action arose under the Patent Act, 35 U.S.C. § 1, *et seq*.; the Copyright Act, 17 U.S.C. § 101, *et seq*.; and the Lanham Act, 15 U.S.C. § 1051, *et seq*.; and because the New York state law claims formed part of the same case or controversy. Defendant-Appellee BestMed, LLC ("BestMed") brought counterclaims for a declaratory judgment of patent non-infringement, patent invalidity, and unenforceability, as well as for false patent marking. The District Court had subject matter over BestMed's counterclaims under 28 U.S.C. § 1331 and 28 U.S.C. § 1338. This Court has jurisdiction over this appeal pursuant to 28 U.S.C.

§§ 1291 & 1295(a)(1) in that it is an appeal from a final judgment in a case disposing of all parties' claims in a case arising in part under the Patent Act.

Following trial, the District Court issued an opinion and order resolving the parties' post-trial motions on May 15, 2013; entered judgment on May 21, 2013; and entered an amended judgment on June 11, 2013. This appeal, filed on June 13, 2013, is timely. 28 U.S.C. § 2107(a); FED. R. APP. P. 4.

STATEMENT OF THE ISSUES

1. Whether the District Court erred in granting BestMed's post-trial motion for Judgment as a Matter of Law ("JMOL") with respect to: (a) patent invalidity when BestMed failed to move for JMOL on patent invalidity pre-verdict; and (b) unjust enrichment on grounds that were not raised by BestMed when it moved for JMOL pre-verdict.

2. Whether the District Court erred in granting JMOL as to patent invalidity and declaring the asserted claims of Medisim's U.S. Patent No. 7,597,668 (the "'668 Patent") anticipated over Medisim's FHT-1 device, where the District Court disregarded the jury's factual findings and credibility determinations, improperly weighed evidence and assessed witness credibility, mischaracterized and misunderstood the relevant technology, and erroneously shifted the burden to Medisim to demonstrate validity of the asserted claims.

3. Whether the District Court erred in granting JMOL on Medisim's unjust enrichment claim arising from BestMed's unauthorized use of Medisim's proprietary, non-public information to Medisim's detriment as preempted by Medisim's patent infringement claim and despite the introduction of sufficient evidence of Medisim's damages unique to BestMed's unjust enrichment.

4. Whether the District Court erred in conditionally granting a new trial without justification and for the purpose of subverting any reversal by this Court of the District Court's grant of JMOL on the basis that BestMed was procedurally barred from raising a JMOL motion post-trial.

5. Whether the District Court erred in denying some of Medisim's motions for post-trial relief in light of its grant of JMOL in favor of BestMed.

STATEMENT OF THE CASE

A. PRELIMINARY STATEMENT

At the conclusion of a nine-day trial, a jury unanimously ratified the judgment of the U.S. Patent and Trademark Office (the "PTO") that Moshe Yarden, the inventor of the '668 Patent, developed an invention worthy of patent protection. This recognition is far from surprising given that the thermometric device that is the subject of the '668 Patent was a significant advancement in the thermometry field.

Medisim, the assignee of the '668 Patent, sought damages and injunctive relief against BestMed for infringement of the '668 Patent and on other non-patent claims. The jury determined that Medisim was entitled to relief and, among other things, awarded Medisim monetary damages on its patent infringement and New York state unjust enrichment claims.

However, despite BestMed's waiver of its right to raise a post-verdict motion for JMOL on numerous issues, the District Court overturned the verdict. Specifically, the District Court erroneously determined that the asserted claims of the '668 Patent are invalid due to anticipation, and that Medisim's unjust enrichment claim was preempted by its patent infringement claim. This ruling effectively vacated the jury's damages award to Medisim, but was procedurally improper.

In addition to the procedural deficiencies, the District Court's judgment is wholly unsupported on the merits. Contrary to the District Court's assertions, there is no prior art embodying all the limitations of the asserted claims, much less a sale, offer for sale, or use of a device embodying all the limitations of such claims. The District Court also erroneously believed that Medisim's unjust enrichment claim was preempted by its patent infringement claim, and that Medisim failed to establish it otherwise was entitled to relief under such a claim.

Further compounding its errors, the District Court conditionally granted a new trial without any justification other than to circumvent any ruling by this Court that BestMed is procedurally barred from seeking JMOL. Indeed, the District Court admitted it would entertain renewed summary judgment motions before the commencement of any new trial, and strongly suggested it would reach the same conclusion regarding anticipation as it did on JMOL.

Finally, the District Court abused its discretion by declining to address the merits of Medisim's post-trial motions as a consequence of its grant of JMOL in BestMed's favor.

Accordingly, Medisim was denied almost all of the relief afforded by the verdict. The errors of the District Court cannot be sustained, and this Court should reinstate the jury verdict and grant Medisim corresponding relief.

B. PROCEDURAL HISTORY AND DISPOSITION BELOW

On November 28, 2012, the District Court dismissed various claims on summary judgment. A2473-547. Prior to trial, BestMed voluntarily dismissed its false patent marking counterclaims. A9515. During trial, the District Court determined that Medisim was not entitled to damages on its New York unfair competition claim. A4395-97.

Following the nine-day trial, the jury reached the following conclusions:

- None of the asserted claims of the '668 Patent are invalid;[1]
- BestMed was liable for direct infringement, induced infringement, and contributory infringement of the asserted claims of the '668 Patent;
- BestMed's infringement was willful;
- BestMed was unjustly enriched under New York law;
- BestMed infringed Medisim's rights of copyright; and
- BestMed had not engaged in unfair competition under New York law.

A6138-46. The jury awarded Medisim $1.2 million in patent infringement damages, and $2.29 million in damages for unjust enrichment. A6145-46. The District Court entered the jury verdict on February 11, 2013, but stayed execution of the judgment pending disposition of post-trial motions. A2897.

In its post-trial motions, BestMed sought JMOL on grounds of patent invalidity and unjust enrichment that were not the subject of its pre-verdict JMOL motions. A4676-77. The District Court denied Medisim's request to strike portions of BestMed's post-trial brief in light of this deficiency. A61-66.

On May 15, 2013, the District Court issued an opinion and order resolving the post-trial motions. A67-135. The District Court denied Medisim's requests for

[1] Medisim asserted claims 1, 8-12, 15, 19, 21, 27, 32, 35-37 of the '668 Patent against BestMed. A2618.

post-trial relief except for a grant of injunctive relief on its copyright infringement claim. A134. However, the District Court granted JMOL of invalidity to BestMed on the basis that the "'668 Patent is invalid as anticipated."[2] A134. The District Court also granted JMOL for BestMed on unjust enrichment, eviscerating the jury's award of monetary damages to Medisim. A134. Finally, the District Court granted a new trial "conditioned on an appellate court determining that [BestMed] failed to preserve its right to bring a post-trial motion for JMOL." A120.

The Clerk entered judgment on May 21, 2013. A136-37. On June 6, 2013, the District Court amended this judgment to reflect that its decision only concerned the asserted claims of the '668 Patent, A143-44, which the Clerk entered on June 11, 2013. A145-46.

STATEMENT OF THE FACTS

A. MEDISIM'S THERMOMETRIC TECHNOLOGY

Core body temperature, the temperature of blood flowing through the pulmonary artery, is widely accepted as a valuable temperature for assessing and treating illness. A72; A1090. The '668 Patent, filed on May 31, 2006 and issued on October 6, 2009, is directed to a fast non-invasive thermometric device that displays a reasonable approximation of core body temperature. A189-98. The claimed device is placed against an external skin surface, takes temperature

[2] The District Court relied, in part, upon prior *Daubert* rulings. A1-49; A50-60.

readings from one or more temperature sensors, determines time-dependent parameters of temperature change responsive to those readings, and calculates a deep tissue temperature (also referred to as a "local" or "local body" temperature). A193. The device then calculates a core body temperature by correcting for the difference between the deep tissue temperature and the core body temperature. A193. Among other things, the invention of the '668 Patent delineates the difference between core body temperature and deep tissue temperature, a distinction that was not recognized in the prior art. A8439.

The '668 Patent incorporates by reference U.S. Patent No. 6,280,397 ("the '397 Patent"). A193. The '397 Patent concerns a temperature measuring device with at least two temperature sensors that calculates body temperature through heat flux. A2987; A6200-06. Heat flux relates to the amount of energy that passes through a given area for a particular period of time.[3] A2986. Notably, unlike the '668 Patent, the '397 Patent does not concern a device that calculates a core body temperature by correcting for the difference between a calculated deep tissue temperature and the core body temperature. A6200-06.

Moshe Yarden, a founder of Medisim, is the inventor of the '668 Patent and one of the inventors of the '397 Patent. A189; A6200. On May 20, 2004, Mr.

[3] Medisim referred to its heat flux technology with the acronym R.A.T.E.®, which stands for "Rapid Accurate Temperature Establishment." A2988-90. Medisim used this trademark to identify the source of goods in marketing materials. A2988-90; A4455.

Yarden – along with Manashe Barak – filed U.S. Patent Application No. 60/572,651(the "'651 Provisional"). A1853-55; A8250-304. The '651 Provisional, considered by the PTO during prosecution of the '668 Patent, contained disclosures of three discrete temperature measurement methods: (a) an infrared radiation reading device that measures the heat flux and surface temperature from the body through a patch; (b) a system of continually monitoring human body temperature via a patch sensing module connected to a wireless reader where temperature is calculated based on heat flux; and (c) a device containing a probe that calculates body temperature based on heat flux. A8250-51; A8276; A8292-93. The '651 Provisional also references Medisim's FHT-1 thermometer, which employs the technology of the '397 Patent. A8292-95. Critically, the '651 Provisional does not refer to an embodiment disclosing a calculation of a deep tissue temperature, a correction to core body temperature from that deep tissue temperature, and time-dependent parameters of temperature change as claimed in the '668 Patent.

Medisim, the assignee of the '668 Patent and the '397 Patent, manufactures and sells thermometric devices. A189; A6200. One such device, the FHT-1 thermometer, was developed prior to the invention of the '668 Patent. A3017. As Mr. Yarden, its inventor, explained, that device calculated a delta with the output of a heat flux based calculation, A3017-18, which represented the difference

between an uncalculated fixed baseline temperature (corresponding to the lower end of possible core body temperatures) and the display temperature. A3017-18. The fixed baseline temperature value in the FHT-1 device is not a measured deep tissue temperature, but rather is a uniform value for all individuals. A3018.

Medisim subsequently developed different thermometers – the FHT-1A, the FHT-5, the FHT-6, and the "Mother's Touch" devices – which practice the '668 Patent. A3019; A3023. Unlike the FHT-1 device that uses an uncalculated fixed baseline value, these newer devices calculate a deep tissue temperature from temperature readings at the external skin surface specific to each individual. *See* A3019; A3023-24. These thermometers then perform an additional calculation which corrects from this calculated deep tissue temperature to a reasonable approximation of core body temperature. *See* A3019; A3023.

B. BESTMED'S MISAPPROPRIATION AND MISUSE OF MEDISIM'S PROPRIETARY TECHNICAL INFORMATION

Medisim sought to manufacture and distribute products that embodied its patented technology, but did not have an extensive distribution network in the United States. A3025-27; A3229. In 2003, Medisim pursued a relationship with BestMed, an established medical products distributor, for the purpose of distributing Medisim's products. A3025-27; A3297.

In November 2004, BestMed and Medisim entered into a fixed thirty-month International Distributorship Agreement (the "IDA") to govern BestMed's sale of

Medisim's conductive forehead thermometers in the United States. A3040-41; A3044-45; A6159-77. Following expiration of the IDA, Medisim continued to supply BestMed with thermometers, and the parties subsequently entered into a Purchase and Sale Agreement (the "PSA") that maintained BestMed's distribution of Medisim's thermometric devices. A3094-95; A9311-12. The PSA commenced on May 1, 2008 and terminated on May 1, 2009. A9311. Medisim sold the FHT-1 and FHT-1A devices to BestMed pursuant to these agreements. A3043.

In its relationship with BestMed, Medisim provided BestMed with proprietary information critical to the successful development and testing of conductive forehead thermometers. The largest customers in the thermometry market (such as Walgreens or CVS) will not purchase a thermometer unless it passes certain tests. A3038; A3052; A3054. Likewise, the U.S. Food and Drug Administration (the "FDA") considers testing under the standards of ASTM International (f/k/a the American Society for Testing and Materials) in approving thermometric products for market in the United States. *See* A3427; A6596-97; A6738-40; A9166-69.

Third parties, such as Schuster Labs, perform these tests in a controlled water bath environment, and hence they are referred to as "water bath" tests. A3053. Water bath tests focus on the "precise temperature as sensed by the sensor" of the thermometer, and thus not necessarily the thermometer's ability to

accurately read a patient's temperature in a clinical setting. A3054. For thermometers like the FHT-1 and FHT-1A devices, which display a temperature different from the one initially sensed, water bath tests are challenging because their standard operation will not produce an accurate reading of the temperature sensor(s). A3053-54.

In light of this challenge, Medisim created a separate operation mode (referred to as "technician" or "test" mode) that a skilled technician can trigger to disable the normal operation of the thermometer, causing it to display not the calculated temperature, but rather simply the temperature value sensed by the device's sensor(s). A3053. Correspondingly, Medisim developed a "water bath testing protocol" that provided specific instructions on how to place the device in technician mode and effectively conduct the water bath test. A6869-74. The creation of a technician mode, and the corresponding protocol for water bath testing in that mode, is proprietary to Medisim. A3055.

In January 2005, in response to BestMed's request, Medisim provided its water bath testing protocol to BestMed to assist BestMed in successfully passing Schuster Labs testing of the Medisim devices in test mode. A6869-74. However, even with the protocol, BestMed still encountered difficulty in testing these devices. A3440-42; A6227. As a result, Medisim provided BestMed with additional information and assistance. A3056-58. With the benefit of Medisim's

input, BestMed finally was able to pass the Schuster Labs testing and secure the ability to sell Medisim's thermometers in the United States. A3058-59; A6192-94.

Medisim provided this non-public information to BestMed in confidence and solely for the benefit of the parties in furthering their business relationship. A3222. After the relationship ended, however, BestMed improperly used Medisim's proprietary information to sell other thermometer products that were developed and tested with the benefit of Medisim's water bath testing information. Namely, BestMed's thermometers from successor manufacturer K-Jump Health Co. Ltd. ("K-Jump") featured a similar technician mode, triggered in the same manner as in the Medisim thermometers, A3444-46, and underwent Schuster Labs testing using Medisim's proprietary water bath testing protocol. A3380-81; A3465; A3625-26; A3653-54; A6578-82; A7910. Indeed, BestMed specifically requested the inclusion of this technician mode in the replacement K-Jump thermometers and provided K-Jump with instructions for successfully water bath testing these devices with this feature implemented. A4041-43. These BestMed-distributed thermometers from K-Jump, embodying the benefits of Medisim's proprietary, non-public information, were first sold in 2009, after the expiration of the PSA. A3479.

Because successful Schuster Labs testing is a prerequisite to a customer's willingness to purchase a thermometer product, A3038; A3052; A3054; A3626,

and is used to secure approval from the FDA to sell these products, *see* A6596-697; A6738-740, BestMed's ability to pass this test was critical to its ability to sell the replacement K-Jump thermometers. Moreover, by using Medisim's proprietary information to coopt Medisim's opportunity to make these same sales for which Medisim was actively competing, A3245; A3260-61, BestMed deprived Medisim of economic benefit. Through these actions, BestMed earned gross profits exceeding $4.6 million dollars. A3864-66. However, in returning a verdict for Medisim on unjust enrichment, the jury awarded Medisim only a portion of BestMed's total profits – *i.e.*, $2.29 million dollars. A4666; A6146.

SUMMARY OF THE ARGUMENT

The District Court improperly granted JMOL for BestMed. First and foremost, BestMed did not preserve its ability to move for JMOL post-trial under FED. R. CIV. P. 50(b) as to patent invalidity and unjust enrichment on the grounds adopted by the District Court in its opinion and order. In fact, prior to submission of the case to the jury, BestMed not only failed to raise a JMOL motion with respect to anticipation, but it failed to move for JMOL on any theory of invalidity. Similarly, although BestMed did move for JMOL on unjust enrichment under FED. R. CIV. P. 50(a), it did so on grounds that were not included in its later motion for JMOL under FED. R. CIV. P. 50(b), and which did not serve as the basis for the District Court's decision. Since BestMed waived its right to obtain JMOL on the

grounds set forth by the District Court, the jury's verdict as to these claims should be reinstated.

Even if BestMed's failure to properly move for JMOL is disregarded, the District Court still erred in overturning the jury's verdict. With regard to anticipation, the District Court incorrectly ignored the jury's findings of fact and witness credibility determinations, and improperly placed a burden on Medisim to prove that the claims of the '668 Patent are valid. Not only did the District Court fail to perform an analysis of all of the relevant claim limitations, it also neglected to recognize that BestMed failed to present evidence indicating that all asserted claims are invalid due to anticipation. Furthermore, the District Court did not consider the full disclosure of the '668 Patent, or its file history, and misconstrued how the accused anticipating FHT-1 device functions. Instead, the District Court focused on irrelevant materials and disregarded evidence that supports the jury's conclusions. In particular, the District Court failed to appreciate that the FHT-1 device does not calculate a deep tissue temperature and then calculate a core body temperature by correcting from deep tissue temperature as required in the '668 Patent claims.

Likewise, aside from the procedural bar, granting JMOL on the unjust enrichment claim was unwarranted on the merits. The District Court mischaracterized Medisim's unjust enrichment claim and erroneously ruled it was

preempted by Medisim's patent infringement claim. But there was no overlap whatsoever between these two claims because Medisim's unjust enrichment claim was predicated upon BestMed's misappropriation of Medisim's proprietary technical information, and not upon the use of Medisim's patented technology. Moreover, contrary to the District Court's contentions, Medisim established that it incurred damages unique to the unjust enrichment claim and in an amount that reflected BestMed's improper gains from the unauthorized use of Medisim's proprietary, but non-patented, information.

Finally, the District Court erroneously granted a conditional new trial and failed to consider and rule upon the merits of Medisim's motions for post-trial relief. The District Court did not provide justification for granting a conditional new trial, indicating only that this ruling was a means of circumventing a reversal by this Court on the basis that BestMed was procedurally barred from raising its post-trial JMOL motion. A new trial is inappropriate here. Moreover, in light of the District Court's improvident rulings on JMOL and conditional new trial, this Court should vacate these rulings and remand to the District Court with instructions to reinstate the jury's verdict and damages award and to address the merits of Medisim's post-trial motions.

ARGUMENT

I. THE GRANT OF A MOTION FOR JUDGMENT AS A MATTER OF LAW IS REVIEWED *DE NOVO* WITH THE EVIDENCE CONSIDERED IN THE LIGHT MOST FAVORABLE TO MEDISIM

"The grant or denial of a motion for judgment as a matter of law is a procedural issue not unique to patent law, reviewed under the law of the regional circuit in which the appeal from the district court would usually lie." *ACCO Brands, Inc. v. ABA Locks Mfr. Co., Ltd.*, 501 F.3d 1307, 1311 (Fed. Cir. 2007) (citation omitted); *see also Transocean Offshore Deepwater Drilling Co. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1356 (Fed. Cir. 2012). The Second Circuit reviews "a district court's resolution of a motion for judgment as a matter of law" *de novo* and applies "the same standard as the district court itself was required to apply." *Diesel v. Town of Lewisboro*, 232 F.3d 92, 103 (2d Cir. 2000) (citations omitted).

In doing so, the Second Circuit will "consider the evidence in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences from the evidence that the jury might have drawn in that party's favor," *id.* (citation omitted), but "cannot assess the weight of conflicting evidence, pass on the credibility of the witnesses, or substitute its judgment for that of the jury." *LeBlanc-Sternberg v. Fletcher*, 67 F.3d 412, 429 (2d Cir. 1995) (citations omitted). A motion for JMOL overturning a jury verdict should not be granted

unless there was "such a complete absence of evidence supporting the verdict that the jury's findings could only have been the result of sheer surmise and conjecture, or . . . such an overwhelming amount of evidence in favor of the movant that reasonable and fair minded men could not arrive at a verdict against [the moving party]." *Song v. Ives Labs., Inc.*, 957 F.2d 1041, 1046 (2d Cir. 1992) (citations omitted).

II. THE TRIAL COURT IMPROPERLY GRANTED BESTMED'S POST-VERDICT MOTION FOR JUDGMENT AS A MATTER OF LAW ON GROUNDS NOT RAISED IN ITS PRE-VERDICT MOTIONS

A post-verdict motion for JMOL "may not be made on grounds not included in the earlier [JMOL] motion." *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1105 (Fed. Cir. 2003); *accord McCardle v. Haddad*, 131 F.3d 43, 51 (2d Cir. 1997); *see also* FED. R. CIV. P. 50.[4] As the Supreme Court has explained, "[a] motion under Rule 50(b) is *not allowed* unless the movant sought relief on similar grounds under Rule 50(a) before the case was submitted to the jury." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486 n.5 (2008) (emphasis added). Indeed, in light of the Seventh Amendment, it is "constitutionally impermissible" for a trial

[4] Regional circuit law generally applies to the Court's review of whether BestMed properly moved for JMOL under FED. R. CIV. P. 50. *See Duro-Last*, 321 F.3d at 1106. However, to the extent the Court's review concerns issues of patent law, Federal Circuit law applies. *See id.* Under both Second Circuit and Federal Circuit law, BestMed waived its right to move for JMOL on grounds that it did not raise in its pre-verdict motions.

court "to re-examine the jury's verdict and to enter JMOL on grounds not raised in the pre-verdict JMOL." *Duro-Last*, 321 F.3d at 1107.

Although BestMed moved for JMOL pre-verdict on some grounds, it did not move on any grounds whatsoever concerning invalidity. A4108-43. Only when faced with a jury verdict for Medisim did BestMed elect to seek JMOL on invalidity. A4676-77. Because BestMed failed to move for JMOL on patent invalidity alleging anticipation under FED. R. CIV. P. 50(a), it was foreclosed from doing so under FED. R. CIV. P. 50(b). In view of Medisim's objections, the District Court should have refrained from ruling on any validity issues after the jury verdict.

Similarly, although BestMed did move for JMOL on the unjust enrichment claim prior to the verdict, the basis for its pre-verdict motion on this claim bears no resemblance to the basis for its post-verdict motion. A litigant cannot preserve its right to JMOL post-verdict by merely invoking a legal theory when moving for JMOL prior to the verdict. *See Samuels v. Air Transp. Local 504*, 992 F.2d 12, 15 (2d Cir. 1993). Especially where, as here, there are a number of legal theories that could support a JMOL motion as to a given claim, a litigant is obliged to sufficiently detail which grounds support its pre-verdict motion. *See id.* Because FED. R. CIV. P. 50(a) was designed to put a party on notice as to potential claim deficiencies and provide that party an opportunity to cure before submission of

such claims to a jury, allowing a party to raise new grounds under FED. R. CIV. P. 50(b) is improper. *See Smith v. Lightning Bolt Productions, Inc.*, 861 F.2d 363, 367 (2d Cir. 1988).

Before the jury verdict was rendered, BestMed moved for JMOL on the unjust enrichment claim only on the grounds that (a) Medisim made no showing that BestMed benefitted at Medisim's expense, A4141; and (b) Mr. Wilson, Medisim's president of its U.S. operations, used Medisim's prior relationship with BestMed to gain entry into the marketplace. A4142-43. However, after the verdict, BestMed repackaged its JMOL motion on unjust enrichment to contend that "there is insufficient evidence to support the jury's verdict on unjust enrichment in light of the IDA and PSA, and the jury's verdict on unfair competition." A130. Compounding the errors, the District Court then granted BestMed's JMOL on the unjust enrichment claim not on these newly-raised grounds, but rather on a ground raised *sua sponte* by the District Court itself – *i.e.*, that the unjust enrichment claim is preempted by Medisim's patent infringement claim. A130-32. Accordingly, prior to the verdict, Medisim had no notice of, and was unable to address, these new arguments.

Thus, the District Court erred in granting BestMed's post-trial JMOL motion on grounds concerning invalidity and unjust enrichment that were not raised in BestMed's pre-verdict motion.

III. THE DISTRICT COURT INCORRECTLY DETERMINED THAT THE ASSERTED CLAIMS OF THE '668 PATENT ARE ANTICIPATED BY THE FHT-1 DEVICE

A. The District Court Disregarded the Jury's Factual Finding that the FHT-1 Device Was Not Anticipating Prior Art

Even if it was appropriate for the District Court to entertain BestMed's motion for JMOL as to patent invalidity despite the procedural bar, it is clear that the asserted claims of the '668 Patent are not anticipated. Because BestMed did not properly move for JMOL on invalidity, this Court's review is limited to whether the District Court's legal conclusions were correct, based upon the presumed factual findings of the jury. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 845 (Fed. Cir. 2010), *aff'd*, 131 S. Ct. 2238 (2011). However, in this case, the jury "made no explicit factual findings," so the Court must presume that the jury resolved factual disputes in favor of Medisim. *Id.* at 846; *Duro-Last*, 321 F.3d at 1108; *see also Jurgens v. McKasy,* 927 F.2d 1552, 1557 (Fed. Cir. 1991) ("Where a directed verdict motion is not made at the close of the evidence, the sufficiency of the evidence underlying presumed jury findings cannot be challenged through a [JMOL] motion or on appeal.") (citations omitted).

"Anticipation under 35 U.S.C. § 102 is a question of fact." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (citation omitted). A patent claim is anticipated when a single prior art reference describes "each and every claim limitation and enable[s] one of skill in the art to

practice an embodiment of the claimed invention without undue experimentation." *Id*. (citations omitted). Correspondingly, a patent claim is anticipated when all of the elements of that claim are present in a single device that is sold, offered for sale, or in use more than one year before the filing date of the patent application. *See Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383 (Fed. Cir. 1999) ("the first determination in the § 102(b) analysis must be whether the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention"); *see also* 35 U.S.C. § 102(b). Whether a patent claim is invalid for a public use or sale is a question of law, reviewed *de novo*, based on underlying facts, normally reviewed for substantial evidence following a jury verdict. *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002).[5]

Because the Court's review is limited to whether a legal conclusion of invalidity is warranted in light of the jury's factual findings, the Court must presume that the jury resolved questions of fact relevant to anticipation in favor of Medisim. *See i4i*, 598 F.3d at 845-46. Accordingly, in light of the jury's verdict,

[5] The District Court did not clearly indicate whether it determined that the asserted claims were anticipated under 35 U.S.C. § 102(a) or 35 U.S.C. § 102(b). In fact, the District Court quoted 35 U.S.C. § 102(a), as amended by the Leahy-Smith America Invents Act (the "AIA"), in its opinion and order. A117. The 2011 amendment to 35 U.S.C. § 102, as well as the subsequent 2012 amendment, are not applicable here. *See* Pub. L. No. 112-211, Title I, § 103; Pub. L. No. 112-29, § 3(n).

A6142-43, the Court must acknowledge that the jury determined there is no enabling prior art which describes all of the limitations of the asserted claims and no device embodying the invention of the asserted claims sold, offered for sale or used prior to the critical date. Specifically, in this case, the jury determined that the FHT-1 thermometer does not embody all of the elements of any of the asserted claims. A6142-43.

The District Court simply ignored the jury's findings of fact and usurped the fact-finding role of the jury. Furthermore, in reaching its erroneous determination of anticipation, the District Court offered no element by element analysis, ignored claim limitations of the '668 Patent, disregarded evidence put forth by Medisim, and failed to provide any support for its legal conclusions. Indeed, as emblematic of its approach, the District Court initially invalidated all claims of the '668 Patent, not just the claims asserted at trial. A134. Unlike the District Court, this Court should honor the jury's implicit factual findings, and restore the validity of the '668 Patent claims.

B. The District Court Improperly Weighed Evidence, Assessed the Credibility of Witnesses, and Shifted the Burden to Medisim to Establish that the FHT-1 Device Did Not Anticipate the Asserted Claims of the '668 Patent

Not only did the District Court improperly assume the fact finder role, it incorrectly shifted the burden to Medisim regarding validity. Each claim of a patent shall be presumed valid. 35 U.S.C. § 282. In light of this presumption, the

party challenging validity has the burden of establishing that a claim is invalid by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011).

Nevertheless, in granting JMOL for BestMed, the District Court stated that "[o]ne problem common to both Lipson and Yarden's testimony is that, while both offer conclusory denials that the intermediate temperature of the FHT-1 is a deep tissue temperature, neither provides a convincing account of what the intermediate temperature actually *is*." A124. Thus, the District Court not only impermissibly weighed evidence and assessed credibility, but more fundamentally placed the burden on Medisim to establish that the FHT-1 device *does not* practice the asserted claims of the '668 Patent. The burden of demonstrating anticipation rested solely with BestMed, and should not have been shifted to Medisim.

Nonetheless, Medisim presented substantial evidence at trial to rebut BestMed's contention that the FHT-1 device calculates deep tissue temperature as required by the asserted claims of the '668 Patent. *See Minn. Mining & Mfg. Co.*, 303 F.3d at 1301. Indeed, the testimony of Mr. Yarden, inventor of the '668 Patent and the FHT-1 device, *see* A2991; A3017-19; A3171-75, was itself sufficient to rebut BestMed's claim that the FHT-1 practices the asserted claims. *See i4i.*, 598 F.3d at 847 (there is "no corroboration requirement for inventor testimony asserted

to defend against a finding of invalidity by pointing to deficiencies in the prior art").

But in addition to Mr. Yarden's testimony, the jury was presented with testimony from Dr. Lipson, Medisim's technical expert, who established that BestMed's invalidity allegations are incorrect. A4423-27. The District Court recognized that both Mr. Yarden and Dr. Lipson explained why the asserted claims are valid, but improperly discredited that testimony. A124-25. Although BestMed attempted to prove that the asserted claims are anticipated by way of expert testimony, the jury was free to disregard this testimony while crediting the testimony of Medisim's witnesses. The District Court should not have overridden the jury's weighing of witness credibility.

C. BestMed Failed to Meet Its Burden to Establish that the Asserted Claims of the '668 Patent are Anticipated by the FHT-1 Device

BestMed had the burden of establishing by clear and convincing evidence that the FHT-1 device met all of the limitations of the asserted claims. Anticipation requires strict identity, as opposed to similarity, between the prior art and the invention, and accordingly, anticipation is "quite rare." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296-97 (Fed. Cir. 2002). The District Court mistakenly believed that the sole issue in dispute on the merits of anticipation post-trial was "whether the FHT-1 meets the deep tissue temperature limitation of the '668 Patent." A119. However, as Dr. Lipson testified, there are at least two claim

limitations absent from the FHT-1 device. A4423-25. Indeed, the focus of the District Court should have been on whether there was a "complete absence of evidence supporting the verdict" or such an overwhelming amount of evidence that "reasonable and fair minded" jurors could not have concluded the asserted claims are valid. *See Song*, 957 F.2d 1041.

While the District Court focused on the deep tissue temperature limitation, BestMed still had the obligation to demonstrate that *all* of the limitations of *all* of the asserted claims were met by the FHT-1 device, yet BestMed failed to satisfy this burden. In particular, BestMed was unable to establish that the FHT-1 device first calculates a "deep tissue temperature" and then calculates a core body temperature "by correcting for a difference between the core body temperature and the deep tissue temperature," A197-98, a failure the District Court did not acknowledge. *See Scaltech*, 178 F.3d at 1383.

BestMed's failure to meet this burden at trial is exacerbated by the District Court's inappropriate efforts to reach a contrary conclusion. In its misguided attempt, the District Court marshaled the following evidence from the summary judgment proceedings: (a) opinions of Mr. Goldberg, BestMed's technical expert; (b) Mr. Yarden's deposition testimony; (c) Medisim's marketing descriptions of its technology; and (d) the disclosure of the '651 Provisional. A91. The District

Court contended that all of this evidence except the '651 Provisional "ultimately reached the jury in pertinent part." A91.

Although it was "unnecessary to resolving" BestMed's motion for JMOL, the District Court took judicial notice of the '651 Provisional and concluded that it "strongly suggests that the FHT-1 thermometer anticipates the '668 Patent." A92-93. However, the '651 Provisional, which was considered by the PTO during prosecution of the '668 Patent, does not disclose the limitations of the asserted claims of the '668 Patent, including those for calculating a deep tissue temperature and correcting from that deep tissue temperature to calculate a core body temperature. The District Court also concluded, without citation, that "[n]otably, all of the features that Yarden described as essential to his innovation are present in the '651 Provisional," A97, yet failed to explain where this information is set forth and apparently disregarded that the application consists of three distinct disclosures. A8250; A8275; A8292. More fundamentally, however, the District Court wrongly asserted that the '651 Provisional was "presented to the jury by way of the parties' experts' reports," A91-92, because the parties' expert reports were not admitted in evidence at trial.

The District Court also cataloged the following trial evidence supporting its view that BestMed met its obligation to establish that the FHT-1 device anticipates the asserted claims of the '668 Patent: (a) testimony of Mr. Yarden and Dr. Lipson;

(b) testimony of Mr. Goldberg; (c) evidence relating to Medisim's pre-litigation descriptions of its technology; and (d) "evidence relating to the shift between the FHT-1 and the FHT-1A, which Medisim contends was the first thermometer to embody the '668 Patent." A95. Medisim addresses the issues most central to the District Court's reasoning below.

1. The District Court Neglected to Acknowledge that BestMed Failed to Address All Claim Limitations

While the District Court recognized that "[t]ypically, testimony concerning anticipation must be testimony from one skilled in the art" and must, among other things, "explain in detail how each claim element is disclosed" in the supposed anticipating device, it ignored BestMed's failure to meet these requirements. A118 (quoting *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002). When granting JMOL for BestMed on anticipation, the District Court incorrectly stated that BestMed's technical expert, Mr. Goldberg, testified that "the FHT-1 met all the claim limitations of the '668 Patent." A104. Mr. Goldberg only testified – albeit incorrectly – that *some* of the asserted claims of the '668 Patent are anticipated by the FHT-1 device.[6] Accordingly, the expert testimony relied upon by the District Court does not even address all of the asserted claims. A4092-102.

[6] Mr. Goldberg's anticipation testimony solely addressed claims 1, 8, 15, 19, 21, 27, 32, 35, 36, and 37 of the '668 Patent. He did not testify that claims 9, 10, 11, and 12 of the '668 Patent are anticipated. A4092-102.

Furthermore, the "[g]eneral and conclusory testimony" offered by BestMed's expert "does not suffice as substantial evidence of invalidity." *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1152 (Fed. Cir. 2004). Mr. Goldberg's anticipation testimony was bereft of significant analysis, and he relied heavily on the written conclusions of a non-testifying "expert" of dubious expertise. A4221; A4225; A4228. This non-testifying expert supposedly analyzed the source code of the FHT-1 device, yet Mr. Goldberg could not identify which sections of this purported expert's written report corresponded to the limitations of the asserted claims. A4226-27. Accordingly, the District Court's reliance on Mr. Goldberg's testimony that the FHT-1 device calculates a deep tissue temperature as set forth in the asserted claims of the '668 Patent is unsupported.

Additionally, the District Court neglected to consider BestMed's failure to establish that the FHT-1 device meets all of the *other* limitations of the asserted claims of the '668 Patent. Indeed, the District Court pointed to no evidence showing that BestMed met its burden to demonstrate that the FHT-1 device calculates a core body temperature by correcting for a difference between deep tissue temperature and core body temperature. A68; A197-98.

Again, BestMed relied exclusively on the testimony of Mr. Goldberg who, while noting that he did not "want to have to go through all the detail," stated only that the FHT-1 supposedly "performs the calculations that yield[] the display of

core temperature." A4087. Mr. Goldberg later testified, without support, that because the FHT-1 device supposedly "calculates deep tissue temperature" and "displays core body temperature," the correction limitation of the claims is satisfied. A4098. Yet Mr. Goldberg did not expand upon his superficial analysis, instead insisting that "we know that [the FHT-1 device] calculates a deep tissue temperature, and we know that it corrects to core" without further explanation. A4101. As the jury must have concluded, Mr. Goldberg's conclusory testimony does not establish that the correction limitation of the asserted claims is met by the FHT-1 device, particularly because it is based upon the incorrect assumption that the device calculates a deep tissue temperature. Every limitation must be met by the prior art device, and BestMed's unsupported contention that the FHT-1 device meets the correction limitation is insufficient.

2. The District Court Erroneously Concluded that Evidence Regarding a "Third-Order Polynomial" Provided Support for a Finding of Anticipation

The District Court contends that Mr. Goldberg "identified for the jury a portion of the source-code of the FHT-1 that is consistent with the '668's teachings for arriving at a deep tissue temperature." A105. However, contrary to the District Court's assertions, Mr. Goldberg simply testified that the FHT-1 device implements a third-order polynomial and referenced some undefined portion of the FHT-1 source code as his support. A4101.

However, not all third-order polynomials are created equal. Indeed, Mr. Goldberg himself testified that polynomials yield different results and that all polynomials are not the same. A4311-13. Mr. Goldberg's conclusory assertion that the FHT-1 device meets limitations of the asserted claims for employing some type of polynomial that any predictive device may use is, at best, a generalized statement of non-technical information that falls short of the type of clear and convincing evidence establishing invalidity. *See Microsoft Corp.*, 131 S. Ct. at 2242. Indeed, the jury correctly recognized this deficiency by disregarding Mr. Goldberg's testimony.[7]

The District Court also inappropriately noted Mr. Goldberg's out of context assertion that Mr. Yarden testified during a deposition that a third-order polynomial is used by the FHT-1 device. A121-22. Yet it ignored that on direct examination, Mr. Goldberg conceded that Mr. Yarden further explained during this same deposition that the FHT-1 device does not calculate core body temperature by correcting for a difference between core body temperature and deep tissue

[7] The District Court commented that Medisim's cross-examination of Mr. Goldberg "did not bear fruit." A105. As the finder of fact in this case, the jury, not the District Court, was tasked with determining whether cross-examination was effective. *LeBlanc-Sternberg*, 67 F.3d at 429. Since the jury determined that none of the asserted claims of the '668 patent are invalid, the jury must have discredited Mr. Goldberg's testimony.

temperature. A4255-56. This is another example of the District Court improperly weighing testimony to further BestMed's invalidity position.

3. The District Court Improperly Concluded That Medisim's Marketing Documents Establish that the Asserted Claims are Anticipated

In addition to erroneously adopting Mr. Goldberg's incorrect conclusions, the District Court appeared to base its opinion on marketing documents that addressed technology developed by Medisim before the application for the '668 Patent was filed. A107-08. These documents, which in some cases are undated, contain nothing but a generalized, non-technical description of some of Medisim's invasive and non-invasive technology; are not tied to the '668 Patent claims; and do not disclose all of the clam limitations or the arrangement of the limitations. Accordingly, these documents have no bearing on whether the claims of the '668 Patent are anticipated.

The District Court also incorrectly implied that Medisim's use of the R.A.T.E.® trademark to describe its commercial products has a bearing on anticipation. A122-23. A trademark, however, simply is an identifier of the source of goods or services and has no meaning as to functionality. 15 U.S.C. §§ 1052 & 1127; *Christian Louboutin S.A. v. Yves Saint Laurent Am. Holding, Inc.*, 696 F.3d 206, 218 (2nd Cir. 2012) (citing *Qualitex Co. v. Jacobson Products Co.*, 514 U.S. 159, 165 (1995)). At trial, both Mr. Yarden and Dr. Lipson established that

R.A.T.E.® is just a term to generally identify several Medisim products. A2988-90; A4455. In fact, the '651 Provisional provides support that several versions of technology use the R.A.T.E.® mark as demonstrated by the reference to version 3.0 in the application. A2988-89; A8292.

Furthermore, the marketing documents do not indicate that a product associated with the R.A.T.E.® trademark must practice the claims of the '668 Patent. Specifically, the District Court referred to a product outline Medisim sent to BestMed in 2003, and erroneously implied that this document demonstrated that the invention of the '668 Patent could be practiced solely with devices that Medisim characterized as using "R.A.T.E.®" technology. A106-07. However, the outline refers to invasive thermometers as well as a temperature under the skin and therefore, contrary to the District Court's interpretation, does not demonstrate that a R.A.T.E.® device calculates the deep tissue temperature identified in the '668 Patent. A9461. Moreover, the District Court identified a diagram of a cross-section of skin in this product outline in support of its conclusion.[8] *See* A107. While this diagram contains a section labeled "Deep tissues," there is no indication that this is a reference to "deep tissue" temperature of the '668 Patent or that the

[8] Although the District Court referred to a diagram in the product outline, it appears that it cited to the incorrect page of that document. *See* A107; A9456; A9458.

temperature referenced in this section must be calculated.[9] A9456. Finally, the documents do not disclose a correction from deep tissue temperature to core body temperature, indicating that these two terms were used synonymously.

The District Court also misconstrued a different, undated Medisim product outline, *see* A107-08, mistakenly interpreting this outline's reference to "deep tissues' temperature" and Medisim's FHT thermometer line to indicate that the FHT-1 device practices the '668 Patent. A122-23; A8081. However, as Mr. Yarden testified, this document merely distinguishes Medisim's conduction-based technology from infrared technology. *See* A3205-06. Mr. Yarden further explained that this comparison has nothing to do with the deep tissue temperature limitation of the '668 Patent. A3206-07. The jury acted within its discretion in properly crediting Mr. Yarden's explanation of these materials.[10]

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[9] The District Court also contended that the product outline indicates that R.A.T.E.® technology must use a heat flux algorithm taught by the '397 Patent. *See* A106. However, the District Court did not point to any evidence demonstrating that the '397 Patent algorithm must be used to calculate the deep tissue temperature referenced in the claims of the '668 Patent.

[10] Although the District Court claimed to credit the jury's implicit findings that Medisim's pre-litigation documents do not indicate that the FHT-1 device embodies the invention of the '668 Patent, it nevertheless concluded that "because the underlying physical process described by Medisim's marketing documents corresponds to the deep tissue temperature limitation, a reasonable jury would necessarily find these documents corroborative of anticipation." A123. These documents do not mention the FHT-1 device, and District Court again substituted its judgment for that of the jury.

In sum, the District Court failed to recognize that materials concerning Medisim's R.A.T.E.® technology do not indicate that the FHT-1 device anticipates the asserted claims of the '668 Patent. Instead, it adopted BestMed's litigation-inspired theory that references to a trademark somehow indicate that the technology of the patent was incorporated into the FHT-1 device. However, the jury recognized that Medisim's R.A.T.E.® trademark does not describe the invention of the '668 Patent, and the District Court erred in supplanting its view for the jury's conclusion.

4. The District Court Erred by Attaching Significance to the FHT-1A Device Which Was Not the Alleged Anticipating Prior Art

The District Court also focused on the supposed absence of evidence "marking the switch from the FHT-1 to the FHT-1A," the supposed "absence of evidence that the source code of the FHT-1A differed from that of the FHT-1," and the supposed lack of evidence concerning the operation and sales of the FHT-1A device in determining that the asserted claims are anticipated. A123-24. This focus on the FHT-1A device was misplaced. The pertinent analysis involves just the FHT-1 device – the only alleged anticipating prior art – and whether that device met all of the limitations of the asserted claims. *See Scaltech Inc.*, 178 F.3d at 1383.

Even so, the District Court ignored a significant amount of evidence establishing that Medisim notified BestMed of the change in supply from the FHT-1 device to the FHT-1A device, and that the FHT-1 device differed from the FHT-1A device. *See, e.g.*, A3078; A3019. Mr. Yarden, the inventor of these devices, testified that they do not use the same source code. A3019-20. Moreover, even though BestMed could have introduced evidence regarding the supposed similarity of the FHT-1 and FHT-1A devices, its expert did not testify regarding this issue at trial or present an analysis of the FHT-1A source code. In any event, Medisim was not required to affirmatively establish any of these contentions for which the District Court noted an absence of evidence.

5. The District Court Misunderstood the Functionality of the FHT-1 Device When Considering Whether this Device Anticipated the Asserted Claims of the '668 Patent

The District Court also inexplicably asserted that "intrinsic evidence" indicates that the asserted claims of the '668 Patent are anticipated. A121. This erroneous contention is based upon the District Court's mistaken belief that "the '668 Patent makes it abundantly clear that deep tissue temperature may be derived from the '397 algorithm," and that because the FHT-1 "implements the '397 algorithm," it must perform the deep tissue temperature limitation of the claims of the '668 Patent. A121. This logic is faulty, however, because it is based on the incorrect assumption that T_{avg} (a variable in the empirically-derived formula for

core body temperature disclosed in the '668 Patent) is the "local body temperature" of the '668 Patent. A82.

The '668 Patent instead indicates that T_{avg} is the heat-flux derived temperature of the '397 Patent, which can then be used to calculate deep tissue temperature with the teachings of the '668 Patent.[11] A197; A222; *see* A3013. Indeed, there is nothing in the '668 Patent that indicates T_{avg} itself is deep tissue temperature. *See* A222. To the contrary, Mr. Yarden explained that T_{avg} is a variable incorporated into a third-order polynomial used to calculate deep tissue temperature in the '668 Patent, A3012, but his testimony was improperly dismissed in favor of the District Court's misinterpretation. A127-28.

At trial, Mr. Yarden further explained that the FHT-1 device uses the algorithm of the '397 Patent, and its T_{avg} output, in an entirely different way than the '668 Patent. Instead of calculating a deep tissue temperature, the FHT-1 device uses the '397 Patent to calculate a "delta" that is applied to a "given base line." A3174-75; *see* A3017-18. Indeed, the source code of the FHT-1 device itself indicates that this delta corresponds to "T_{avg}-27," which is far less than any body temperature. A9299-300. Again, the method of operation of the FHT-1 device is completely different from that disclosed and claimed in the '668 Patent. There is

[11] The '397 Patent describes "a method for rapidly determining core body temperature based on heat flux . . . when [a] thermometer is inserted into an orifice of the body. A3012-13.

simply no evidence that the aforementioned "delta," "base line" value, or output of the '397 algorithm corresponds to deep tissue temperature.

By virtue of its verdict, the jury accepted Mr. Yarden's explanation that the FHT-1 device employed an "uncalculated" fixed baseline along with the heat flux algorithm of the '397 Patent to display an approximation of core body temperature. *See i4i*, 598 F.3d at 846 (the Court must presume that the jury resolved factual disputes in favor of the party that prevailed at trial). Mr. Yarden even explained that a shortcoming of this methodology – namely, that it has some inherent unreliability because the same baseline is used for all individuals – led to the invention of the '668 Patent. A3003-04; A3017-18. Accordingly, Mr. Yarden clearly explained why the FHT-1 device does not practice the invention of the '668 Patent. Nonetheless, the District Court improperly disregarded the jury's acceptance of Mr. Yarden's explanation, and instead substituted its own interpretation. A121-22; *LeBlanc-Sternberg*, 67 F.3d at 429.

In the process, the District Court attempted to diminish the significance of Mr. Yarden's testimony by claiming that it relates to his subjective understanding of the '668 Patent. A127. However, the District Court ignored that Mr. Yarden's testimony concerning the FHT-1 device is especially relevant because he invented that device. Indeed, the District Court ruled pre-trial that Mr. Yarden was permitted to provide testimony at trial on technical issues such as this that are

within the realm of his personal knowledge. A2528. The jury was free to accept or reject his testimony, and in fact deemed it to be credible.

The District Court rather focused on the testimony of Mr. Goldberg, even though he misconstrued and mischaracterized Mr. Yarden's deposition testimony on this issue to support BestMed's contention of anticipation. The District Court blindly adopted Mr. Goldberg's faulty argument as the basis for its conclusion as to the significance of T_{avg}, implicitly and inappropriately weighing the credibility of Mr. Goldberg and Mr. Yarden after the jury already had determined that Mr. Yarden was more credible.

Moreover, the District Court inappropriately disregarded the testimony of Medisim's technical expert Dr. Lipson. *See* A126. Dr. Lipson explained that the FHT-1 calculates an "intermediate" temperature value that is not "local deep tissue temperature." A4455-56. He advised that this opinion was informed by a number of sources, including his review of the algorithms in the underlying FHT-1 software, conversations with Mr. Yarden about the functionality of the device, marketing literature, and his own testing of the device. A4424-25.

When testing the FHT-1 device, Dr. Lipson placed the thermometer in test mode (which converts the thermometer from a predictive to a real-time device) and held it against his temple for several minutes until it reached an actual equilibrium temperature. A4424-25. He explained that this equilibrium temperature differed

from the result of the intermediate temperature value calculation by the FHT-1 algorithm.[12] A4424-25. Such a testing methodology was based not only upon Dr. Lipson's own expertise, but also upon the work of other experts in the field of thermometry as well as the testimony of Emory Hsu, an engineer at BestMed's successor thermometer supplier K-Jump. A3989-90. Accordingly, there was an abundance of testimony that the jury could – and did – choose to credit in finding that the FHT-1 device did not calculate deep tissue temperature and did not correct to core body temperature. *See, e.g.,* A4441.

6. The District Court's Interpretation of *Daubert* Weighs Against Anticipation

This Court applies the law of the regional circuit when deciding evidentiary issues, including whether a district court's decision to exclude expert testimony was correct. *See Research Corp. Techs., Inc. v. Microsoft Corp*., 536 F.3d 1247, 1255 (Fed. Cir. 2008). The District Court's evidentiary rulings are reviewed for abuse of discretion. *United States v. Mercado*, 573 F.3d 138, 141 (2d Cir. 2009); *see Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141–43 (1997).

[12] The District Court claimed that Dr. Lipson testified that the sole difference between the FHT-1 thermometer and the claims of the '668 patent was that the thermometer did not calculate deep tissue temperature. A103. However, the District Court mischaracterized Dr. Lipson's testimony, which was given in response to an ambiguous hypothetical question, while disregarding the entirety and context of Dr. Lipson's opinions. A4438-42. Specifically, the District Court ignored that Dr. Lipson testified that the FHT-1 does not practice all of the limitations of the asserted claims of the '668 patent. A4441.

As an initial matter, BestMed failed to object to any of Dr. Lipson's testimony on the basis that it was precluded by the District Court's *Daubert* decision. Because BestMed failed to object, it has waived its ability to challenge Dr. Lipson's testimony on *Daubert* grounds. *See Port Auth. Police Asian Jade Soc'y of New York & New Jersey, Inc. v. Port Auth. of New York & New Jersey*, 681 F. Supp. 2d 456, 466 (S.D.N.Y. 2010) (citing *United States v. Yu-Leung*, 51 F.3d 1116, 1121 (2d Cir. 1995)). But even if BestMed objected to Dr. Lipson's testimony on the grounds that it was precluded under *Daubert*, its objection would have been unwarranted. The District Court's *Daubert* decisions were limited and did not address Dr. Lipson's anticipation opinions. A32-41; A53-56.

Furthermore, Dr. Lipson's forehead test utilizing the FHT-1 device was based upon a sound scientific methodology, *see* A4424-25, and there was no reason to place any limitation on the admissibility of testimony concerning the results of that test or any of Dr. Lipson's tests. The District Court's implication that such testing was flawed is based upon the incorrect reasoning found in its *Daubert* ruling. Specifically, the District Court incorrectly believed that "the thermo-equilibrium temperature at the skin's surface is not equivalent to deep tissue temperature." A126.

In reaching this conclusion, the District Court relied upon the publications of Sessler and Yamakage/Namiki, A34, and mistakenly determined that deep tissue

temperature can only be measured with the zero-heat-flux method. A34; A53-54. However, the authors of these publications – which pre-date the '668 Patent – failed to distinguish core body temperature from deep tissue temperature and, thus, were not using these terms in the same manner as used in the '668 Patent. A1312-13; A1315. The '668 Patent contributed to the art by dispelling such confusion and clearly distinguishing core body temperature from deep tissue temperature. *See, e.g.*, A193. The District Court did not appreciate this difference. The District Court did not point to any materials indicating that the deep tissue temperature referenced in the '668 Patent – *i.e.*, "a temperature at a location under the skin that is the source of heat conducted to the sensors in the probe" of a device – could not be obtained by placing a probe on the skin to measure the thermo-equilibrium temperature. A193.

Ironically, if the District Court's *Daubert* decisions are correct, they undermine its own conclusion regarding anticipation. In its *Daubert* decisions, the District Court determined that calculating a deep tissue temperature by measuring the thermo-equilibrium temperature at the skin's surface was possible *only* through the zero-heat-flux method, which required at least two thermistors and a heating element. A35. There was no evidence presented at trial that the FHT-1 device utilizes a heating element; in fact, it does not. Thus, under the District Court's own

Daubert decision, the FHT-1 device could not possibly calculate deep tissue temperature and, hence, could not anticipate the '668 Patent.

Based on the record at trial, a reasonable jury could have concluded that BestMed failed to prove by clear and convincing evidence that the asserted claims of the '668 Patent are invalid due to anticipation in view of the FHT-1 device. It was impermissible for the District Court to usurp the role of the jury to reach a contrary conclusion. Accordingly, the District Court's grant of BestMed's motion for JMOL as to invalidity must be reversed.

IV. THE DISTRICT COURT INCORRECTLY DETERMINED THAT BESTMED WAS ENTITLED TO JUDGMENT AS A MATTER OF LAW ON MEDISIM'S UNJUST ENRICHMENT CLAIM BECAUSE THAT CLAIM WAS PREEMPTED BY MEDISIM'S PATENT INFRINGEMENT CLAIM

In granting JMOL for BestMed on the grounds that Medisim's claim for New York state unjust enrichment was preempted by the patent laws, the District Court fundamentally misconstrued both the law and facts governing Medisim's claim.

A preemption analysis begins with the Supremacy Clause, under which "it has been settled that state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citations omitted). Preemption by federal law takes three basic forms: "First, Congress may explicitly preempt state law; second, a federal scheme may occupy a given field and thus

preempt state law in that field; and third, when compliance with both state and federal law is impossible, the conflicting state law is preempted." *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1305 (Fed. Cir. 2003). Whether a state law claim is preempted by federal law is a question of law reviewed *de novo* according to the law of the Federal Circuit. *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed. Cir. 2005) (citations omitted)).

Medisim's claim for unjust enrichment arose under New York law. "New York precedent establishes that unjust enrichment includes 'that (1) the other party was enriched, (2) at that party's expense, and (3) that it is against equity and good conscience to permit the other party to retain what is sought to be recovered.'" *Hall v. Bed Bath & Beyond, Inc.*, 705 F.3d 1357, 1369-70 (Fed. Cir. 2013) (quoting *Georgia Malone & Co. v. Rieder*, 19 N.Y.3d 511, 516 (N.Y. 2012)). Specifically, Medisim's unjust enrichment claim is based on the enrichment that BestMed obtained from selling thermometers developed through the unauthorized use of Medisim's proprietary, non-public information, to Medisim's detriment. Notably, Medisim's unjust enrichment claim has nothing to do with the asserted patent claims or the technology disclosed in any of Medisim's patents.

It is well-settled that a state law claim for unjust enrichment presents neither explicit nor field preemption issues. *Ultra-Precision*, 411 F.3d at 1377. Thus, the

only potential preemption of Medisim's unjust enrichment claim arises in the context of "conflict" preemption.

Conflict preemption occurs only if "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives' of Congress." *Ultra-Precision*, 411 F.3d at 1377 (citations omitted). In other words, "a state may not offer patent-like protection to intellectual creations that would otherwise remain unprotected as a matter of federal law." *Am. Cyanamid*, 342 F.3d at 1305 (citing *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989)). However, a state claim is not "patent-like" simply because it touches upon patents. *See*, *e.g.*, *Am. Cyanamid*, 342 F.3d at 1306.

Most notably, in *American Cyanamid*, this Court held that an unjust enrichment claim arising under Colorado law was not in conflict preemption with the patent laws. In that case, this Court determined that the plaintiffs' "right involved here and compensated for under a theory of unjust enrichment . . . is not 'patent-like' at all [because] 'the unjust enrichment claim springs not from an attempt to enforce intellectual property rights, but instead from Cyanamid's alleged wrongful use of the [plaintiffs'] research results.'" *Am. Cyanamid*, 342 F.3d at 1306 (citing *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 196 F.3d 1366, 1371-72 (Fed. Cir. 1999)). As such, the plaintiffs' unjust enrichment claim did "not undermine the purposes of the federal patent scheme" and, thus, "[t]here

[was] no patent law preemption." *Am. Cynamid*, 342 F.3d at 1307. Accordingly, unjust enrichment in the form of Cyanamid's incremental profits deemed attributable to its securing a patent using the plaintiffs' confidential information was permissible. *Id*.

On the opposite end of the spectrum stands *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369 (Fed. Cir. 2005). In *Ultra-Precision*, the plaintiff sought unjust enrichment under Michigan law based on Ford's use of the plaintiff's technical information. *Ultra-Precision*, 411 F.3d at 1377. Unlike in *American Cyanamid*, however, the information that Ford used was disclosed and available to the public. *Ultra-Precision*, 411 F.3d at 1380. Accordingly, to the extent Ultra-Precision sought a "patent-like remedy for Ford's conduct in making, using, and selling products embodying information Ultra-Precision was not successful in protecting under the federal patent laws[,]" and "[i]n the absence of an incremental benefit conferred," this Court held Ultra-Precision's unjust enrichment claim to be preempted. *Id.* at 1382.

Medisim established at trial that while successful water bath testing was a prerequisite to selling thermometers in the United States, it was a particular challenge for the FHT-1 and FHT-1A devices because the temperature displayed by those devices is a calculated approximation of core body temperature rather

than the temperature measured at the surface of the skin, and thus meaningless for the purpose of water bath testing. A3053-54.

Medisim solved this problem by developing and implementing a technician mode which overrode the normal operation of these thermometers such that the display temperature also would be the temperature value measured by the devices' sensors. A3053. Medisim even created an entire protocol for water bath testing that provided specific instructions on implementing technician mode as well as additional information to successfully perform the water bath testing. A6869-74. At trial, Mr. Yarden explained that this collective water bath test information was a closely-held and valuable know how of Medisim, and therefore not disclosed in any Medisim patents:

> This is a very unique know how that we developed in Medisim in order to comply with the standard. It was going back into the, even the invasive thermometers that we, we couldn't, because of the heat flux method, we couldn't use them as is into the water bath, so we had to have this specific technician mode. As that's why we developed it. And this is something that we developed it, and it is well related to our product, products. And it is a kind of know how. *It is not protected in any patent, because it should not be disclosed to the public*. It is just with our customers under nondisclosure on [sic] under confidentiality agreement.

A3055-56 (emphasis added).

BestMed needed the collective water bath test information from Medisim in order to pass the Schuster Labs testing and sell these devices in the United States.

A3038; A3052; A3054; A3427; A6596-597; A6738-740. In response to BestMed's request, Medisim provided BestMed not only with a copy of the proprietary water bath test protocol, A6869-74, but also with additional information and assistance to allow BestMed to overcome the problems it was experiencing. A3056-58. With the benefit of Medisim's information, BestMed finally was able to pass the Schuster Labs testing and sell the Medisim thermometers. A3058-59; A6192-94.

Medisim provided this information to BestMed in confidence and solely for the benefit of Medisim and BestMed in furthering their business relationship. A3222. Nevertheless, BestMed disseminated this proprietary information to K-Jump to incorporate a nearly-identical technician mode in replacement thermometers that K-Jump provided to BestMed after BestMed ended its relationship with Medisim. A3444-46; A4041-43. Furthermore, BestMed used Medisim's water bath test protocol to successfully conduct testing on these replacement K-Jump thermometers so that BestMed could sell them in the United States. A3380-81; A3625-26; A3653-54; A3465; A6578-82; A7910. Such misappropriation and misuse of the collective water bath test information by BestMed directly caused Medisim to lose sales of its thermometers to the replacement thermometers manufactured by K-Jump.

Accordingly, Medisim's claim for unjust enrichment is much more closely analogous to the successful claimant in *American Cyanamid* than to the preempted claimant in *Ultra-Precision*.[13] Like the plaintiffs in *American Cyanamid*, Medisim provided BestMed with proprietary information under the expectation that it would be kept private between the parties, but that information was later used by BestMed to secure a benefit at the expense – and to the exclusion – of Medisim. Additionally, unlike the publicly-disclosed information at issue in *Ultra-Precision*, the water bath testing information that Medisim provided was not the subject of any patents and was not otherwise disclosed to the public.

Finally, as in *American Cyanamid*, the jury did not provide a "patent-like" remedy that awarded all of BestMed's profits as damages for unjust enrichment. Instead, the jury awarded only that portion of BestMed's total profits that it found were attributable to the unjust enrichment; indeed, the jury specifically stated that its unjust enrichment damages were *not* attributable to patent infringement and were meant to be awarded separately. A4666-67. There is no preemption of Medisim's unjust enrichment claim by the patent laws on these facts.

[13] The elements for unjust enrichment under Colorado law are similar to New York law. *Compare Am. Cyanamid*, 342 F.3d at 1309 (unjust enrichment in Colorado) *with Hall*, 705 F.3d at 1369-70 (unjust enrichment in New York). Likewise, New York recognizes unjust enrichment based on the misappropriation of information. *See*, *e.g.*, *Saunders v. Kline*, 55 A.D. 2d 887, 888 (N.Y. App. Div. 1977); *see generally Hall*, 705 F.3d at 1371.

In granting JMOL, the District Court misconstrued Medisim's unjust enrichment claim in a manner that created preemption that otherwise did not exist. The District Court erroneously described Medisim's unjust enrichment claim as follows:

> Now that Medisim's attempt to gain a monopoly through the patent law has proved unavailing, it cannot argue that it should nevertheless receive the same protection through the state law of unjust enrichment. A quasi-contract granting Medisim patent-like protection over its invalidated patent would usurp the federal patent law, and for this reason, the jury's verdict on unjust enrichment must be overturned.

A131.

However, as demonstrated above, Medisim's claim is not an attempt to seek compensation for the use of its patented technology, or even of the non-patented information disclosed in its patent. *Supra*, pp. 46-48. To the contrary, Medisim's unjust enrichment claim stems from BestMed's misuse of Medisim's proprietary, non-public information and know-how that was deliberately neither claimed nor disclosed in the '668 Patent or any other Medisim patent. A3055-56. There was ample evidence on the nature of this proprietary Medisim information and BestMed's subsequent use of it in launching its sales of K-Jump's replacement thermometers. *Supra*, pp. 10-14. Thus, BestMed received an incremental benefit above and beyond that covered by the '668 Patent. *See Am. Cyanamid*, 342 F.3d at 1311-12.

Moreover, the District Court improperly viewed Medisim's unjust enrichment claim as somehow contingent upon the outcome of Medisim's separate patent infringement and unfair competition claims. A112 ("Medisim's claim for unjust enrichment . . . fell in the interstices of its claims for patent infringement, copyright infringement, unfair competition (state and federal), false advertising (state and federal), and Deceptive Acts and Practices"); A130-31 ("*In light of* my holding that the '668 Patent is invalid, *and* the jury's verdict of no unfair competition, an unjust enrichment claim cannot arise out of BestMed's sales of the accused products subsequent to the expiration of the PSA.") (emphasis added).

Medisim's unjust enrichment claim, however, is an independent cause of action that is in no way dependent upon the outcome of any of its other claims. Indeed, for the District Court to suggest otherwise would require that the unjust enrichment claim be expressly preempted by the patent laws, a proposition that this Court has elsewhere rejected. *See Ultra-Precision*, 411 F.3d at 1377. Thus, the jury's verdict on unfair competition and the District Court's post-trial ruling on invalidity have no bearing upon Medisim's unjust enrichment claim.

The District Court also cites its jury instruction on unjust enrichment as compelling preemption. Specifically, in granting JMOL, the District Court reasoned that the jury "was instructed that it could only find unjust enrichment based upon BestMed's sales of the accused products" and thus that "the jury's

verdict of unjust enrichment was grounded solely on BestMed's sales of the accused products." A130. However, this instruction cannot be construed to mean that the jury was precluded from considering all the facts presented at trial regarding BestMed's eventual sales of non-Medisim thermometers in reaching its verdict on unjust enrichment.

Finally, the District Court was incorrect in concluding that Medisim lacked sufficient evidence on damages. A131-32. At trial, Medisim sought damages for unjust enrichment in the form of disgorgement of BestMed's profits, which is an appropriate remedy for such a claim. *See Am. Cyanamid*, 342 F.3d at 1311-13 (applying Colorado law); *Mass. Eye and Ear Infirmary v. QLT Phototherapeutics, Inc.*, 552 F.3d 47, 67 (1st Cir. 2009) (applying Massachusetts law). New York courts also have concluded that disgorgement of profits is warranted for unjust enrichment. *See Mayer v. Bishop*, 158 A.D. 2d 878, 880 (N.Y. App. Div. 1990); *New York City Econ. Dev. Corp. v. T.C. Foods Imp. & Exp. Co., Inc.*, 819 N.Y.S.2d 849 (N.Y. Sup. Ct. 2006), *aff'd*, 46 A.D.3d 778, 847 N.Y.S.2d 669 (2007). Furthermore, New York courts generally rely upon the RESTATEMENT (THIRD) OF RESTITUTION AND UNJUST ENRICHMENT, *see Eber-NDC, LLC v. Star Indus., Inc.*, 831 N.Y.S.2d 347 (Sup. Ct. 2006), *aff'd as modified*, 42 A.D.3d 873, 839 N.Y.S.2d 650 (2007), which also favors the disgorgement of profits as a remedy for unjust enrichment. *See* RESTATEMENT (THIRD) OF RESTITUTION AND

UNJUST ENRICHMENT §51(4) (2011) ("[T]he unjust enrichment of a conscious wrongdoer, . . . is the net profit attributable to the underlying wrong.").

Medisim's damages expert, Andrew Carter, provided testimony on the calculation of BestMed's profits derived from the sale of its thermometers, which were developed, tested, and brought to market using Medisim's proprietary information. A3864-65. Importantly, the *BestMed* profits calculated by Mr. Carter were different than the amount of *Medisim* lost profits that Mr. Carter separately calculated as a remedy for Medisim's patent infringement claims. *Compare* A3866-68 (calculating $5,604,140 in total Medisim lost profits) *with* A3864-66 (calculating $4,628,349 in BestMed profits). In response, BestMed offered testimony of its damages expert, Robert McSorley, who provided a figure of just $78,397 "attributed to the wrongful conduct." A4325-26; A4361-62.

The competing experts' testimony on the quantum of BestMed profits to be disgorged – coupled with the jury instruction to "consider the value of the benefit that BestMed obtained in order to determine the amount by which BestMed was unjustly enriched," A4629 – provided sufficient information from which the jury could determine the damages attributable to unjust enrichment. The District Court criticized the evidence adduced at trial for failing to explicitly identify the percentage of BestMed's profits deemed attributable to the unjust enrichment, but that criticism is unfounded. *See Russo v. Ballard Med. Prods.*, 550 F.3d 1004,

1018 (10th Cir. 2008) (refusing to reverse jury's award of $17 million for unjust enrichment, which represented the jury's determination that 53% of defendant's profits were attributable to the unjust enrichment when plaintiff valued the unjust enrichment at 100% and defendant valued it at 0%); *Mass. Eye and Ear Infirmary*, 552 F.3d at 68 (affirming jury's determination of unjust enrichment damages based on disgorgement of profits that represented an amount of damages that fell between the parties' competing computations).

It also is clear that the jury's unjust enrichment award did not overlap with its patent damage award. The District Court directed the jury that damages should not be double counted, A3866-67, and the law presumes that the District Court's instructions were followed. *Richardson v. Marsh*, 481 U.S. 200, 206 (1987). Indeed, during the pronouncement of its verdict, the jury specifically stated that the damages for patent infringement and unjust enrichment were meant to be cumulative. A4666-67.

Accordingly, Medisim's claim for unjust enrichment is not preempted by the patent laws, and there was more than sufficient evidence from which the jury could have found for Medisim on unjust enrichment and awarded damages of $2.29 million dollars.

V. THE DISTRICT COURT ABUSED ITS DISCRETION IN CONDITIONALLY GRANTING BESTMED'S MOTION FOR A NEW TRIAL AS A MEANS OF CIRCUMVENTING A REVERSAL BY THIS COURT OF ITS IMPROVIDENT GRANT OF JMOL IN FAVOR OF BESTMED

In addition to reversing the District Court's grant of JMOL on invalidity and unjust enrichment, this Court also should reverse the District Court's grant of a new trial which was "conditioned on an appellate court determining that [BestMed] failed to preserve its right to bring a post-trial motion for JMOL." A120.

Whether a new trial should be granted is a procedural issue not unique to patent law, and thus is determined by the law of the regional circuit. *i4i*, 598 F.3d at 841; *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1374 (Fed. Cir. 2001). In the Second Circuit, "[a] motion for new trial ordinarily should not be granted unless the trial court is convinced that the jury has reached a seriously erroneous result or that the verdict is a miscarriage of justice." *Townsend v. Benjamin Enters., Inc.*, 679 F.3d 41, 51 (2d Cir. 2012). Whether a district court properly granted a new trial is reviewable on appeal under an abuse of discretion standard. *Binder v. Long Island Lighting Co.*, 57 F.3d 193, 202 (2d Cir. 1995).[14] A district court abuses its discretion when "(1) its decision rests on an error of law…or a clearly erroneous factual finding, or (2) its decision – though not

[14] *Binder* was repudiated on other grounds unrelated to the issue of appellate review of conditional new trials. *See Fisher v. Vassar College*, 114 F.3d 1332 (2d Cir. 1997).

necessarily the product of a legal error or a clearly erroneous factual finding – cannot be located within the range of permissible decisions." *Raedle v. Credit Agricole Indosuez*, 670 F.3d 411, 417 (2d Cir. 2012).

Additionally, when the grant of a new trial is conditioned upon reversal of JMOL, the District Court also "must state the grounds for conditionally granting or denying the motion for a new trial." FED. R. CIV. P. 50(c)(1). The grounds offered by the District Court in this regard form the basis for appellate review. *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 206 (3d Cir. 1992) (confining appellate review of conditional grant of a new trial to grounds asserted by district court); *Mears v. Nationwide Mut. Ins. Co.*, 91 F.3d 1118, 1124 (8th Cir. 1996) (same).

Unfortunately, the District Court offered no reason why a new trial was justified. Addressing new trial only in a footnote, the District Court did not provide any legal or evidentiary grounds to support the conditional grant of that motion. Nor did it contend that a new trial was warranted because the jury reached a seriously erroneous result or because the verdict is a miscarriage of justice. That is an abuse of discretion. FED. R. CIV. P. 50(c)(1); *accord Portage II v. Bryant Petroleum Corp.*, 899 F.2d 1514, 1524-25 (6th Cir. 1990) (finding that "[t]he district court's failure to state a basis for conditionally granting the new trial, provides another reason for finding that a new trial is unwarranted"); *Kingsley*

Assocs., Inc. v. Moll Plasticrafters, Inc., 65 F.3d 498, 506 (6th Cir. 1995) (reversing conditional new trial because "the only rationale given for the conditional new trial was that the jury's verdict was against the clear weight of the evidence, without any further elaboration").

Instead, the District Court's sole reason for conditionally granting a new trial was to thwart any contrary decision by this Court that BestMed was procedurally barred from obtaining post-trial JMOL relief. Indeed, the District Court candidly admitted that it has no intention of actually conducting a new trial, and stated its intention to use the guise of new trial to entertain a post-remand summary judgment motion on invalidity if the JMOL is overturned on Rule 50 grounds. A120 (stating that if this Court determined that BestMed "failed to preserve its right to bring a post-trial motion for JMOL," the District Court "will then entertain a motion for summary judgment on anticipation prior to the commencement of a new trial").[15]

Worse yet, the District Court has already pre-judged this summary judgment motion in BestMed's favor. A93-95 (stating that "[h]ad BestMed moved for summary judgment on anticipation . . . it is likely that the motion would have been

[15] The authority cited by the District Court for such a procedure, *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1326 (Fed. Cir. 2012), is inapposite. *ArcelorMittal* concerned a remand to the trial court for further proceedings under the new claim construction issued by this Court on appeal. 700 F.3d at 1326. In contrast, the District Court here intends to employ post-remand summary judgment, on its own accord, to circumvent this Court.

granted" and that "BestMed probably erred by failing to move for summary judgment on anticipation"). Such an abuse of the new trial procedure solely to nullify a ruling by this Court and ensure the District Court's desired outcome provides further reason to reverse. *Portage II*, 899 F.2d at 1524 (characterizing the district court's grant of a post-verdict motion to dismiss and conditional new trial, awarded in a case where the movant failed to seek JMOL pre-verdict, as "manipulat[ing] the Federal Rules").

Accordingly, reversal of the District Court's conditional grant of a new trial pursuant to FED. R. CIV. P. 50(c)(1) is warranted.

VI. THIS COURT SHOULD REMAND FOR A DETERMINATION OF MEDISIM'S ENTITLEMENT TO POST-TRIAL RELIEF

Following the return of the jury's verdict, Medisim brought the following post-trial motions, among others:

- motion for a permanent injunction under 35 U.S.C. § 283 enjoining BestMed from continuing its infringing activities, A181;
- motion for pre-judgment and post-judgment interest on its patent infringement and unjust enrichment claims pursuant to 35 U.S.C. § 284, New York's Civil Practice Law and Rules §§ 5001 and 5002, and 28 U.S.C. § 1961; a finding that the case is "exceptional" and awarding Medisim its attorneys' fees under 35 U.S.C. § 285 and FED. R. CIV. P. 54, taxable costs pursuant to 35 U.S.C. § 284, FED. R. CIV. P. 54, and L. CIV. R. 54.1; and an

accounting of BestMed's pre-injunction sales and supplemental damages pursuant to 35 U.S.C. § 284, A181; and

- motion for a judicial finding of willful infringement and an enhancement of damages pursuant to 35 U.S.C. § 284, A182.

As a result of the District Court's order granting BestMed's motion for JMOL, the District Court denied these post-trial motions as moot or otherwise failed to address them. A132-33.

Medisim is entitled to this requested post-trial relief. The District Court, however, did not address these requests on the merits solely in light of its decision granting BestMed's motion for JMOL on anticipation and unjust enrichment. Such treatment is an abuse of discretion. *See Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 34-38 (Fed. Cir. 2012) (vacating denial of post-trial relief for lack of analysis and remanding for determination on the merits). Accordingly, should this Court reverse the District Court's grant of JMOL on anticipation and unjust enrichment, it also should vacate the District Court's cursory denial of Medisim's post-trial relief and remand for a decision on the merits consistent with this Court's ruling.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

For the foregoing reasons, the District Court improperly granted JMOL on patent invalidity and unjust enrichment not only because BestMed was

procedurally barred from raising these grounds post-trial, but also because the District Court failed to consider the evidence in the light most favorable to Medisim. Instead, the District Court inappropriately weighed evidence, assessed the credibility of witnesses, mischaracterized Medisim's legal claims, misapplied the law to those claims, and shifted the burden of persuasion to Medisim. Furthermore, the District Court erroneously granted a conditional new trial in order to circumvent a ruling by this Court that BestMed had failed to preserve its ability to move for JMOL on patent invalidity and unjust enrichment after the jury verdict. Finally, the District Court neglected to rule on the merits of Medisim's post-trial motions.

This Court should reverse the District Court's grant of JMOL on patent invalidity and unjust enrichment and its grant of a conditional new trial. Correspondingly, this Court should remand to the District Court with instructions to (a) reinstate the jury's verdict in favor of Medisim as to patent invalidity and unjust enrichment; (b) enter judgment in favor Medisim with respect to patent infringement in the amount of $1.2 million; (c) enter judgment in favor of Medisim with respect to unjust enrichment in the amount of $2.29 million; (d) consider and rule on the merits of Medisim's post-trial motions; and (e) afford Medisim all other relief that may be warranted.

Respectfully submitted,

Dated: October 15, 2013

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ADDENDUM 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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MEDISIM LTD.,

Plaintiff,

- against -

BESTMED LLC,

Defendant.

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OPINION AND ORDER

10 Civ. 2463 (SAS)

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

Medisim Ltd. ("Medisim") brings this action against BestMed LLC ("BestMed") for patent and copyright infringement, unfair competition, false designation of origin, false advertising, deceptive acts and practices, unfair competition, and unjust enrichment. Currently before the Court are cross-motions, pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[1] as well as Rules 702 and 403 of the Federal Rules of Evidence, to exclude expert testimony.[2] For the

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[1] 509 U.S. 579 (1993).

[2] *See* Medisim's Memorandum of Law in Support of Its Motion to Disqualify Defendant's Proposed Expert, Jack Goldberg, or, in the Alternative, to Strike Portions of Goldberg's Reports ("Medisim Mem."); BestMed's

reasons given below, the motions are granted in part and denied in part.

II. BACKGROUND

A. Procedural History

In November 2004, BestMed agreed to be the exclusive distributor for various Medisim products in the United States and Canada.[3] Medisim claims that BestMed began discussions with K-Jump Health Co., Ltd. ("K-Jump") to replace a patented Medisim thermometer while its agreement with Medisim was still in effect. As a result of those discussions, Medisim states that BestMed terminated its distribution contract with Medisim in 2009 and began selling a competing product manufactured by K-Jump.[4] BestMed denies these allegations,[5] and this lawsuit followed.

B. The Experts

Medisim seeks to disqualify Jack Goldberg, or, in the alternative to exclude parts of his reports.[6] BestMed seeks to exclude portions of Dr. David

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Memorandum of Law in Support of Its Motion to Strike Portions of Plaintiff's Experts, Lipson and Keegan ("BestMed Mem.").

[3] *See* Complaint ("Compl.") ¶ 9.

[4] *See id.* ¶¶ 11-13.

[5] *See* BestMed Answer, Affirmative Defenses, Counterclaims and Jury Demand ("Answer") ¶ 11.

[6] *See* Medisim Mem. at 1.

Lipson's report, as well as the entire report of Dr. Warren J. Keegan.[7] Each expert's background is described below**.**

1. Jack Goldberg[8]

Goldberg has two degrees in electrical engineering and computer science: a Bachelor's degree received in 1973 and a Master's degree received in 1978. From 1978 to 1984, he worked at various corporations involved in designing scientific equipment, with increasing levels of responsibility. In 1984, Goldberg began working at IVAC – an Eli Lilly subsidiary – on various projects, and served as technical director in the development of a new infrared thermometer. Eventually, he became the supervisor of IVAC's entire line of thermometers. Since leaving IVAC in 1995, Goldberg has served as President of Metronix, Inc. In that role, Goldberg has consulted on various medical equipment projects – including thermometers – as well as software design matters. He has also worked for several hearing aid companies.

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[7] *See* BestMed Mem. at 1.

[8] These facts are drawn from Goldberg's resume. *See* Expert Report of Jack Goldberg Regarding Invalidity and Unenforceability of U.S. Patent No. 7,597,668 and False Patent Marking in Relation to U.S. Patents No. 6,280,397 and 7,597,668 ("Goldberg Report"), Ex. A to Declaration of Richard H. Brown, Attorney for Medisim ("Brown Decl."), at 92-102.

2. Dr. David Lipson[9]

Lipson – the named inventor on nearly thirty U.S. patents – attended Cornell University, which awarded him a Bachelor's Degree in electrical engineering in 1973. He did his graduate work in biomedical engineering at Case Western Reserve University, where he earned a Master's Degree in 1975 and a Ph.D. in 1979. Over the course of his career, he has worked at various medical and pharmaceutical corporations, including Abbott Labs and IVAC, where his tenure briefly overlapped with Goldberg's. He has taught at Cornell University since 2004, and is a Senior Member of the Institute of Electrical and Electronics Engineers.

3. Dr. Warren Keegan[10]

Keegan studied economics at Kansas State University, where he obtained a Bachelor's Degree in 1958 and a Master's Degree the following year. By 1967, he earned two additional degrees – a Master's Degree and a Doctorate – from the Harvard Business School. Keegan has taught at the post-graduate level for the past thirty years at various prestigious institutions, including the Columbia Business School, the George Washington University, the Stern School of Business

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[9] These facts are drawn from Lipson's resumé. *See* Ex. A to Expert Report of David Lipson, Ph.D. ("Lipson Report"), Ex. 1 to BestMed Mem.

[10] These facts are drawn from Keegan's resumé. *See* Ex. 1 to Expert Report of Dr. Warren J. Keegan ("Keegan Report"), Ex. 10 to BestMed Mem.

at NYU, and Pace University, where he now serves as a full professor. He has published many professional and scholarly articles, and is also the author of a marketing management textbook. In the private sector, Keegan has worked as a consultant at various corporations and consultancies, including General Motors and the Boston Consulting Group. He also runs Keegan & Company LLC and Warren Keegan Associates, Inc., which engage in litigation consulting and management consulting, respectively.

C. The Expert Reports

1. Goldberg's Reports

BestMed retained Goldberg primarily to analyze the validity of various claims of U.S. Patent No. 7,597,668 ("the '668 Patent"). In his initial report, Goldberg concluded that the '668 Patent failed the enablement and written description requirements of Section 112 of Chapter 35 of the United States Code,[11] as well as the non-obviousness requirement of Section 103.[12] He also concluded that the '668 Patent was anticipated under Section 102.[13] Finally, Goldberg concluded that Medisim failed to disclose material information to the Patent and Trademark Office, and that it falsely marked several devices in violation of Section

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[11] *See infra* Part III.A.3.

[12] *See infra* Part III.A.4.

[13] *See id.*

292 of Chapter 35 of the United States Code.[14]

In his rebuttal report, Goldberg was asked to respond to the expert report of Andrew Carter, as well as Lipson's report, on the issues of alleged infringement of the '668 Patent and the availability of acceptable non-infringing substitutes.[15] He concluded that the accused BestMed products did not in fact infringe the '668 Patent, and that there were "numerous acceptable non-infringing substitutes for the Patented Technology."[16]

C. The Lipson Report

Medisim retained Lipson "to analyze digital temple thermometers marketed and/or sold by BestMed . . . and to opine on whether such products infringe any claim of . . . the '668 Patent."[17] He concluded that BestMed directly infringed eight claims of the '668 Patent, and induced or contributed to the

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[14] *See* Goldberg Report at 16-20.

[15] *See* Rebuttal Expert Report of Jack Goldberg Regarding the Alleged Infringement of U.S. Patent No. 7,597,668 by BestMed's Products and the Availability of Acceptable Noninfringing Substitutes for the Patented Technology ("Goldberg Rebuttal Report"), Ex. B to Brown Decl., at 4.

[16] *Id.* at 13.

[17] Lipson Report at 2.

infringement of six more.[18] Lipson also wrote a rebuttal to the Goldberg Report.[19]

D. The Keegan Report

Keegan conducted a consumer survey "to determine whether there is a likelihood of confusion among consumers between the plaintiff Medisim's digital temple thermometer and the defendant BestMed's digital temple thermometer."[20] Using an Internet-based survey platform, respondents were randomly assigned to either a test cell or a control cell.[21] Each respondent was shown a picture of a product and directed to "take as much time to look at [it] as you would if you were considering purchasing it."[22] The respondent was then shown another photograph of a different product,[23] and asked two questions. *First*, he was asked if he thought the two products were manufactured by the same company, or by different

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[18] *See id.* at 4-5.

[19] *See* Rebuttal Expert Report of David Lipson, Ph.D., Ex. 3 to Medisim Mem., at 2.

[20] Keegan Report at 1.

[21] *See id.* at 4.

[22] Survey Questionnaire, Ex. 5 to Lipson Report.

[23] Test-cell respondents were shown pictures of a Medisim thermometer and a BestMed thermometer, both in RiteAid branded packaging, while control-cell respondents were shown pictures of a Medisim thermometer and a third-party thermometer. While both thermometers in the control cell were RiteAid branded, the third-party thermometer had to be digitally altered to that effect. *See* Keegan Report at 3.

companies. *Second*, he was asked if he though the two products were manufactured by companies that were affiliated, connected, or associated with one another.[24] Respondents who answered positively to either question were coded as indicating a likelihood of confusion.[25] Using this protocol, Keegan found that eighty-three percent of test cell respondents and fifty-two percent of control cell respondents showed a likelihood of confusion, for a net confusion level of thirty-one percent.[26] On this basis, he concluded that "the difference between the test and control cell results is statistically significant at the 95 percent confidence level [and that] these survey results confirm the presence of a likelihood of confusion in this case."[27]

III. APPLICABLE LAW

A. Admissibility of Expert Testimony Generally

The proponent of expert evidence bears the initial burden of

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[24] *See id.* at 6.

[25] Keegan also used screening questions to ensure that survey respondents(1) were at least eighteen years old, (2) had shopped or were likely to shop at RiteAid, CVS, Walmart, or Walgreens within three months of the survey date, (3) had used an electronic thermometer on themselves or a family member within the past twelve months. *See id.* at 5.

[26] *See id.* at 6.

[27] *Id.* at 6-7.

establishing admissibility by a "preponderance of proof."[28] Federal Rule of Evidence 702 states the requirements for the admission of expert testimony as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Under Rule 702 and *Daubert*, the district court must determine whether the proposed expert testimony "both rests on a reliable foundation and is relevant to the task at hand."[29] That is, the district court must act as "'a gatekeeper to exclude invalid and unreliable expert testimony.'"[30] Nonetheless, "the Federal Rules of

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[28] *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987) (discussing Rule 104(a) of the Federal Rules of Evidence). *Accord Daubert*, 509 U.S. at 592 & n.10 (citing *Bourjaily*, 483 U.S. at 175-76, and explaining that the proponent of expert testimony must prove admissibility by a preponderance of proof).

[29] 509 U.S. at 597. *Accord Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-49 (1999).

[30] *Bickerstaff v. Vassar Coll.*, 196 F.3d 435, 449 (2d Cir. 1999) (quoting *Hollander v. American Cyanamid Co.*, 172 F.3d 192, 202 (2d Cir. 1999)). *Accord Louis Vuitton Malletier v. Dooney & Bourke, Inc.* ("*Vuitton IV*"), 525 F. Supp. 2d 558, 561-65 (S.D.N.Y. 2007) (discussing district court's "special obligation" to gatekeep with respect to expert evidence).

Additionally, expert testimony may not usurp the role of the court in determining the applicable law. *See United States v. Lumpkin*, 192 F.3d 280, 289

Evidence favor the admissibility of expert testimony, and [the court's] role as gatekeeper is not intended to serve as a replacement for the adversary system."[31] Accordingly, in serving as gatekeeper, the court must focus on the principles and methodologies underlying the expert's conclusions, rather than on the conclusions themselves.[32] To this end, courts may consider (1) "whether [the method or theory] can be (and has been) tested," (2) "whether [it] has been subjected to peer review and publication," (3) "the known or potential rate of error [associated with the technique] and the existence and maintenance of standards controlling the technique's operation," and (4) whether the method has achieved "general acceptance" within the relevant community.[33]

The court's objective when exercising this gatekeeping function is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual

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(2d Cir. 1999). Although an expert "may opine on an issue of fact," an expert "may not give testimony stating ultimate legal conclusions based on those facts." *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991). Expert testimony is also inadmissible when it addresses "lay matters which [the trier of fact] is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

[31] *Vuitton IV*, 525 F. Supp. 2d at 562 (citation and quotation marks omitted).

[32] *See Daubert*, 509 U.S. at 595.

[33] *Id.* at 592-95.

rigor that characterizes the practice of an expert in the relevant field."[34] However, recognizing that "there are many different kinds of experts, and many different kinds of expertise," the Supreme Court has emphasized that the reliability inquiry "is a flexible one."[35] Accordingly, the factors "identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[36] Ultimately, the inquiry "depends upon the particular circumstances of the particular case at issue."[37] In sum, the trial court has "the same kind of latitude in deciding *how* to test an expert's reliability . . . as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable."[38]

In addition to the forgoing, Federal Rule of Evidence 403 states that relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it[,] the judge in weighing

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34 *Kumho Tire Co.*, 526 U.S. at 152.

35 *Id.* at 150.

36 *Id.* (quotations omitted).

37 *Id.*

38 *Id.* at 152 (emphasis in original).

possible prejudice against probative force under Rule 403 . . . exercises more control over experts than over lay witnesses."[39]

B. Admissibility of Survey Evidence

Consumer surveys are often used to demonstrate or refute a likelihood of consumer confusion in cases brought under the Lanham Act.[40] Obviously, "[s]urveys do not measure the degree of actual confusion by real consumers making mistaken purchases. Rather surveys create an experimental environment from which we can get useful data from which to make informed inferences about the likelihood that actual confusion will take place."[41]

Reliance on surveys is not without hazards. Indeed, "any survey is of necessity an imperfect mirror of actual customer behavior under real life conditions . . . . It is notoriously easy for one survey expert to appear to tear apart the

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[39] *Id.* (quotation marks omitted).

[40] *See Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 225-28 (2d Cir. 1999).

[41] 6 McCarthy on Trademarks § 32:184 at 32-392. As McCarthy explains, "[d]irect evidence of actual confusion can come only from such sources as misdirected phone calls or letters or even from that rarest of evidence, the testimony of someone willing to testify that they were once a confused customer." *Id.* Although survey evidence is not direct evidence of actual confusion, it is nonetheless routinely categorized "under the heading of 'actual confusion.'" *Id.* at 32-393.

methodology of . . . another."[42] Practically speaking, there is "no such thing as a 'perfect' survey. The nature of the beast is that it is a sample, albeit a scientifically constructed one."[43]

To assess the validity and reliability of a survey, a court should consider a number of criteria, including whether:

> (1) the proper universe was examined and the representative sample was drawn from that universe; (2) the survey's methodology and execution were in accordance with generally accepted standards of objective procedure and statistics in the field of such surveys; (3) the questions were leading or suggestive; (4) the data gathered were accurately reported; and (5) persons conducting the survey were recognized experts.[44]

"[T]he closer the survey methods mirror the situation in which the ordinary person would encounter the trademark, the greater the evidentiary weight of the survey results."[45] The failure of a survey to approximate actual marketplace conditions

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[42] *Id.* § 32:178 at 32-380.

[43] *Id.* at 32-380 to 32-381.

[44] *Louis Vuitton Malletier\ v. Dooney & Bourke, Inc.* ("*Vuitton I*"), 340 F. Supp. 2d 415, 433 (S.D.N.Y. 2004) (citation and alterations omitted), *vacated on other grounds by Vuitton II*, 454 F.3d at 117. *See also* Manual for Complex Litigation § 11.493 at 103 (Federal Judicial Center 4th ed. 2004) (setting out seven criteria); Shari Seidman Diamond, Reference Guide on Survey Research, *in* Reference Manual on Scientific Evidence ("Diamond on Survey Research") at 359, 373-418 (Federal Judicial Center 3d ed. 2011) (discussing criteria to be considered to determine the admissibility of and weight to be accorded to survey evidence).

[45] 6 McCarthy on Trademarks § 32:163 at 32-333.

can provide grounds for inadmissibility.[46] Finally, while errors in survey methodology usually go to weight of the evidence, a survey should be excluded under Rule 702 when it is invalid or unreliable, and/or under Rule 403 when it is likely to be insufficiently probative, unfairly prejudicial, misleading, confusing, or a waste of time.[47]

C. The Enablement Requirement of Patent Law

The so-called "enablement" requirement of patent law is set forth in Section 112 of Chapter 15 of the United States Code, which reads as follows:

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[46] *See Troublé v. Wet Seal*, 179 F. Supp. 2d 291, 308 (S.D.N.Y. 2001) ("Although no survey can construct a perfect replica of 'real world' buying patterns, a survey must use a stimulus that, at a minimum, tests for confusion by roughly simulating marketplace conditions."); *see also American Footwear Corp. v. General Footwear Co. Ltd.*, 609 F.2d 655, 660 n.4 (2d Cir. 1979) (holding district court decision to exclude survey "for failure to conduct it under actual marketing conditions" not clearly erroneous). *But cf. Vista Food Exch., Inc. v. Vistar Corp.*, No. 03-CV-5203, 2005 WL 2371958 at *5-7 (E.D.N.Y. Sept. 27, 2005) (noting that failure to approximate actual marketplace conditions is only one factor amongst many to consider when determining what weight, if any, to give to a survey).

[47] *See Schering*, 189 F.3d at 228; *Starter Corp. v. Converse, Inc.*, 170 F.3d 286, 296-98 (2d Cir. 1999) (affirming district court's exclusion of survey where any probative value was outweighed by prejudicial effect); *Vuitton IV*, 525 F. Supp. 2d at 568 (adopting Special Masters' recommendation to exclude flawed survey under Rules 702 and 403); 6 McCarthy on Trademarks § 32:170 at 32-351 to 32-352 ("In an extreme case, an improperly conducted survey with slanted questions or serious methodological defects may be excludable as 'irrelevant' of the true state of mind of potential purchasers. . . . [However, t]he majority rule is that while technical deficiencies can reduce a survey's weight, they will not prevent the survey from being admitted into evidence.").

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

"To be enabling, a patent's specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation."[48] While courts frequently state that a patent's specification need not disclose what is well-known in the art, the Federal Circuit has firmly established that this "is merely a rule of supplementation, not a substitute for a basic enabling disclosure."[49]

In determining if a patent specification is enabling – that is, if it does not require undue experimentation – courts must balance the so-called *Wands* factors, which include

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability

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[48] *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (citations and quotations omitted).

[49] *Id.*

of the art, and (8) the breadth of the claims.[50]

The Federal Circuit has made clear that these factors are "illustrative, not mandatory."[51] Accordingly, a court need analyze only those *Wands* factors that the facts indicate are relevant.[52]

IV. DISCUSSION

A. Medisim's Motion

1. Goldberg Is Qualified as an Expert

Medisim argues that Goldberg is not qualified as "an expert in the area of digital, conductive thermometry" because he has not worked in the medical device field since leaving IVAC in 1995. It also argues that his experience there was only tangentially related to thermometry, and that he has been "principally a professional expert witness" since then.[53] Accordingly, Medisim asserts that Goldberg's "experience is stale and outdated," and urges this court to exclude his report and prevent him from testifying at trial.[54]

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[50] *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

[51] *Streck, Inc.*, 665 F.3d at 1289 (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)).

[52] *See Amgen, Inc.*, 927 F.2d at 1213.

[53] *See* Medisim Mem. at 1, 7.

[54] *Id.*

Medisim's characterization of Goldberg's tenure at IVAC as tangential to thermometry is misleading for several reasons. *First*, Goldberg led the team that developed IVAC's first infrared digital thermometer. *Second*, he managed IVAC's entire team of thermometry-focused engineers. *Finally*, as a result of his work at IVAC, he was awarded a patent for an infrared thermometer.[55] In sum, Goldberg was deeply involved with thermometry while at IVAC, in a manner more than sufficient to pass muster under Rule 702 and *Daubert*.

Medisim next argues that even if Goldberg *was* an expert, he no longer is today because he "has done no non-litigation expert work involving thermometry for over 15 years."[56] Once again, this argument mischaracterizes the facts. Since leaving IVAC, Goldberg continued to work with medical device manufacturers in a variety of fields and has consulted on several projects directly related to digital conductive thermometry.[57] Furthermore, he did an in-depth review of the general field of thermometry as part of a litigation project that lasted

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[55] *See* BestMed's Memorandum of Law in Opposition to Medisim's Motion to Disqualify Defendant's Proposed Expert, Jack Goldberg, or, in the Alternative, to Strike Portions of Goldberg's Reports ("BestMed Opp. Mem.") at 2-3.

[56] *See* Medisim Mem. at 7.

[57] *See* BestMed Opp. Mem. at 3-4.

from 2002 to 2005.[58] Accordingly, I find that Goldberg's expert qualifications are sufficiently up-to-date, and will not strike his reports for lack of expertise.

2. Goldberg May Rely on the Gilliand Report

Medisim asserts that "Goldberg's references to or testimony about the Gilliand Report [analyzing the source code of the FHT-1]" should be stricken for three reasons:[59] (1) that the Gilliand Report – which was prepared explicitly for this litigation – is not something "that would reasonably be relied upon by experts in the field,"[60] (2) that Goldberg simply parrots Gilliand without applying his own expertise to Gilliand's findings,[61] and (3) that Goldberg's references to the Gilliand

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[58] Medisim argues that much of Goldberg's relevant experience should not be considered because it was not timely disclosed in accordance with this Court's Scheduling Order of May 18, 2010. *See* Medisim Reply Memorandum of Law in Support of Its Motion to Disqualify Defendant's Proposed Expert, Jack Goldberg, or, in the Alternative, to Strike Portions of Goldberg's Reports ("Medisim Rep. Mem.") at 1 (citing Federal Rule of Civil Procedure 26(a)(2)(D)). Under Rule 26(e), however, a party has an ongoing duty to supplement an expert report "in a timely manner if the party learns that in some material respect the disclosure . . . is incomplete . . . ." Prior to the filing of these motions, BestMed could not have known how Medisim would challenge Goldberg's expert qualifications. Now that is has those challenges, BestMed has taken the earliest possible opportunity to respond. Accordingly, BestMed's supplementation is timely, and may be considered on these motions.

[59] Medisim Mem. at 8.

[60] *Id.*

[61] *See id.* at 9-11.

Report amount to improper bolstering.[62]

The suggestion that materials prepared for purposes of litigation do not qualify as facts or data "of a type reasonably relied upon by experts in the field" is unduly restrictive. As the Fifth Circuit has explained, the fact that the report of a consulting expert was prepared "in anticipation of litigation does not mean that it cannot be the type of study an expert would rely upon in expressing his opinion."[63] Instead, a testifying expert may rely on such a report as long as it has sufficient indicia of reliability.[64] Because there is no indication that the Gilliand Report is unreliable, Medisim's first basis to strike references to Gilliand fails.

Where a testifying expert has expertise in the field covered by a consulting expert and independently verifies the latter's conclusions, there is no danger that the former is acting as a mere "mouthpiece or conduit" of the latter.[65] Goldberg is qualified to analyze source code; in fact, he reviewed the same source

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62 *See id.* at 11.

63 *U.S. v. Marine Shale Processors*, 81 F.3d 1361, 1370 (5th Cir. 1996).

64 *See id.*

65 Medisim Mem. at 10.

code documents as Gilliand.[66] Furthermore, the context in which Goldberg refers to the Gilliand Report makes clear that he does so only after analyzing the source code on his own. That he reached the same conclusions as Gilliand does not mean that he "parrots Gilliand's opinion without adding any analysis."[67] Accordingly, Medisim's second basis to strike references to the Gilliand Report also fails.

At bottom, Medisim's effort to strike references to the Gilliand Report rests largely on the misplaced concern that such references amount to improper bolstering. As the Fourth Circuit has explained, referring to the conclusions of a non-testifying expert is improper if done in an attempt to trade on the non-testifying expert's superior professional reputation.[68] Nothing here indicates that Goldberg attempted to take advantage of Gilliand's professional reputation, or that his reputation was superior to Goldberg's in the first place. For this and all the other reasons given above, Goldberg's references to the Gilliand Report will not be stricken.[69]

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[66] *See* Goldberg Report at 107 (listing source code documents considered).

[67] Medisim Mem. at 10.

[68] *See U.S. v. Tran Trong Cuong*, 18 F.3d 1132, 1144 (4th Cir. 1994).

[69] Medisim also argues that disclosing Gilliand's conclusions to the jury would be improper under Federal Rule of Evidence 703, even if the opinions that Goldberg formed based on those conclusions are admissible. *See* Medisim Rep.

3. Goldberg May Provide His Enablement Opinions

Medisim puts forth two reasons to strike Goldberg's enablement opinions. *First*, it complains that Goldberg failed to evaluate the relevant prior art. *Second*, it argues that his conclusion regarding undue experimentation is an unsupported, *ipse dixit* opinion.[70]

a. Goldberg Considered the Relevant Prior Art

Medisim charges Goldberg with failing to consider the Seifert Patent and the Weiss Patent.[71] Lipson, Medisim's expert, argues that a person of ordinary skill in the art would have found these patents, and that they would have led such a person to other materials that would allow him to develop a predictive algorithm for use in a single-sensor conductive thermometer. In other words, these two prior art references would allow a person reasonably skilled in the art to fully implement the '668 Patent.[72]

As noted above, the law of enablement requires that the patent

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Mem. at 3. As there is no indication in the briefs that BestMed intends to introduce the Gilliand Report to explain Goldberg's opinions, the admissibility of the Gilliand Report for that purpose is reserved for trial.

[70] *See* Medisim Mem. at 12-14; *see also* Medisim Rep. Mem. at 5.

[71] *See* Medisim Mem. at 12.

[72] *See* Expert Rebuttal Report of David Lipson, Ph.D. ("Lipson Rebuttal Report"), Ex. 3 to BestMed Mem., at 18.

specification teach a person reasonably skilled in the art how to make and use the claimed invention without resorting to undue experimentation. However, the specification need not explicitly lay out minor details already well-known in the art. BestMed believes that it is improper to refer to the prior art to enable a predictive algorithm for use with single-sensor thermometer because such an algorithm is not a "minor detail," but rather a key feature of the invention claimed in the '668 Patent.[73] Medisim states that BestMed's belief should be rejected as "unsupported attorney argument."[74]

Goldberg expressly states that he considered all of the references listed in Exhibit C of his report, which includes both the Seifert Patent and the Weiss Patent.[75] Because he considered those references and *still* found that the '668 Patent specification did not enable a "one-sensor solution," it is reasonable to infer from his opinions that such a solution is not a "minor detail" that can be taught by referring to prior art, but rather should be described in the specification. While Goldberg did not expressly draw this conclusion, BestMed's argument is far from "unsupported." Accordingly, I find that Goldberg considered the relevant

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[73] *See* BestMed Opp. Mem. at 11.

[74] Medisim Rep. Mem. at 4 (internal quotations omitted).

[75] *See* Goldberg Report at 10.

prior art, and that BestMed's legal arguments on enablement do not exceed the opinions expressed in Goldberg's report.

b. Goldberg's Undue Experimentation Opinions Are Not Mere *Ipse Dixit* Conclusions

Continuing on with its litany of complaints about Goldberg's report, Medisim next argues that Goldberg relied solely on the "quantity of experimentation" factor in forming his opinion that the '668 Patent would require undue experimentation.[76] According to Medisim, "the vast majority of the work [Goldberg] describes is indisputably routine clinical work. . . ."[77] Furthermore, it states that Goldberg's opinion that developing a predictive algorithm for use with a single-sensor thermometer would be difficult is an "*ipse dixit* assertion" and "an unsupported net opinion."[78]

Goldberg's opinion that *deriving* a predictive algorithm for use with a single-sensor thermometer would be difficult is primarily based on the quantity of experimentation that would go into the effort.[79] However, Goldberg's opinion that the task of *validating* that algorithm "would have involved a great amount of

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[76] *See* Medisim Mem. at 13.

[77] *Id.*

[78] *Id.* at 14.

[79] *See* Goldberg Report at 28.

scientific and statistical effort" clearly goes beyond the mere quantity of experimentation and into the other *Wands* factors.[80]

This Court has discretion "to determine whether [an] expert acted reasonably in making assumptions of fact upon which he would base his testimony."[81] Given his expertise in the field of thermometry and his familiarity with other predictive thermometers, I find that Goldberg's determination that validating a predictive algorithm for a single-sensor thermometer would have required "a great amount of scientific and statistical effort" is not a mere *ipse dixit* conclusion. While Medisim may attack Goldberg's opinions in this realm via "[v]igorous cross-examination [and] presentation of contrary evidence," the simple fact that it believes them to be wrong is not grounds to strike them.[82]

4. Goldberg's Anticipation Opinions Are Partially Excluded

a. Goldberg Failed to Apply this Court's Claim Construction When Analyzing the '452 Patent

Medisim argues that Goldberg failed to determine whether the '452 Patent used "core body temperature" to mean "temperature of blood in the

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80 *Id.*

81 *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 22 (2d Cir. 1996).

82 *Daubert*, 509 U.S. at 596.

pulmonary artery," as construed in the *Markman* Order.[83] Goldberg agreed with that construction, calling it the "gold standard" in the field.[84] However, he completely fails to discuss whether the '452 Patent follows that standard. This is problematic, as Goldberg himself admits that "core body temperature" is used inconsistently in the field.[85] Without comparing the use of the term in the two patents, Goldberg's opinion that the '452 Patent anticipates the "calculates a core body temperature" limitation of the '668 Patent lacks a reliable foundation and must be stricken.

b. Goldberg May Testify that the FHT-1 Calculates a Core Body Temperature

In reaching his conclusion that the FHT-1 calculates a core body temperature, Goldberg relies heavily on two pieces of pre-*Markman* evidence: the deposition of Moshe Yarden – inventor of the '668 Patent – and Medisim's answer to a request to admit. In both instances, Medisim made clear that it objected to inquiries related to disputed claim terms, and that it answered subject to that objection.[86] Although BestMed believes that Medisim was required to supplement

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83 *See* Medisim Mem. at 15-16.

84 Goldberg Report at 72 n.12.

85 *See* Goldberg Rebuttal Report at 7.

86 *See* Medisim Mem. at 16-17.

its responses in light of this Court's *Markman* Order, it never sought an order directing Medisim to comply with that request.[87] Furthermore, since July 2011,[88] Medisim has strongly disputed that the *Markman* Order triggered such a duty.[89] Accordingly, BestMed's assertion that Medisim "incredibly" makes this argument for the first time on this motion rings hollow.[90]

The fact that Goldberg relied on arguably outdated materials provided to him by BestMed does not mean that he used unreliable methods. Instead, it indicates that his ultimate conclusions may be incorrect. Such a concern, however, goes to the weight to be accorded an opinion, not to its admissibility. Medisim can fully address its concerns regarding this portion of Goldberg's report on cross-examination, but it will not be stricken on this motion.

c. Goldberg May Testify that the FHT-1 Calculates Deep Tissue Temperature

Goldberg's conclusion that the FHT-1 calculates deep tissue temperature is based primarily on Medisim's admission that the FHT-1 uses its

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[87] *See* BestMed Opp. Mem. at 15 (citing Federal Rule of Civil Procedure 26(e)).

[88] *See* 7/21/11 Letter from Richard Brown, Attorney for Medisim, to Talivadis Cepuritis, Attorney for BestMed, Ex. A to the Second Supplemental Declaration of Richard Brown, at 1-2.

[89] *See* Medisim Mem. at 17.

[90] BestMed Opp. Mem. at 15.

proprietary R.A.T.E. technology. Goldberg explains why he believes the use of R.A.T.E. technology necessarily means that the FHT-1 calculates deep tissue temperature, and supports his opinion with reference to Medisim's own documents and witness testimony.[91] Nonetheless, Medisim complains that Goldberg "has no principled basis to opine that the FHT-1 product calculated a deep tissue temperature,"[92] asserting that Goldberg misused deposition testimony.[93] While Goldberg does cite to Yarden's deposition testimony explaining how the Accused Product infringes the '668 Patent, it was not unreasonable for him to use that deposition testimony when considering the FHT-1. This is so because that testimony involved a discussion of how Medisim's R.A.T.E. technology worked.[94] Accordingly, Goldberg may testify that the FHT-1 calculates a deep tissue temperature.[95]

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[91] *See* Goldberg Report at 39.

[92] *See* Medisim Mem. at 18.

[93] *See id.* at 18-19.

[94] *See* Goldberg Report at 39-40.

[95] Medisim also argues that Goldberg's opinion is internally inconsistent because it equates two different variables with deep tissue temperature. *See* Medisim Mem. at 19. This criticism is misplaced, as it is clear that Goldberg associated the first variable – Tavg – with deep tissue temperature in his analysis *of the '668 Patent*, and associated the second variable – Tavg-27 – with deep tissue temperature in his analysis *of the FHT-1 source code*. *See* Goldberg Report at 41-43.

5. Goldberg May Not Provide His Opinion on Inequitable Conduct

All individuals associated with the filing and prosecution of a patent are under a duty to disclose to the patent examiner all information material to the patentability of the claimed invention. This duty does not extend, however, to prior art already considered by or known to the patent examiner,[96] who is deemed to have considered a reference listed in a search report if she initials the search history containing the reference, or the actual reference itself in the search history.[97]

A party that brings a claim of inequitable conduct based on non–disclosure of prior art must come forward with "clear and convincing evidence . . . that the applicant *made a deliberate decision* to withhold a *known* material reference."[98] Because materiality is determined on a but-for basis, an

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Medisim also suggests that Goldberg's reliance on "physics" is unexplained and should be stricken. *See* Medisim Mem. at 18. An holistic view of Goldberg's report makes it clear that he refers to the heat conduction physics noted in the '398 Patent. *See* Goldberg Report at 12. While Medisim may challenge his understanding and application of those physics via cross-examination, the charge that Goldberg did not explain them is without merit.

[96] *See* 37 C.F.R. § 1.56.

[97] *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1235-36 (Fed. Cir. 2003).

[98] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (emphasis in original).

inequitable conduct claim will fail unless "the PTO would not have allowed a claim had it been aware of the undisclosed prior art."[99]

Goldberg opines that the '668 Patent is unenforceable due to inequitable conduct for two reasons. *First*, he states that "Medisim failed to disclose to the PTO that it sold and offered for sale its own FHT-1 product and that the FHT-1 was in public use prior to May 31, 2005." Because he opined that the FHT-1 would have been material to the prosecution of the '668 Patent, Goldberg concludes that "if the patent examiner had been apprised of the prior art FHT-1 product . . . he would not have allowed the asserted claims of the '668 Patent . . . ."[100] *Second*, Goldberg opines that "the asserted claims of the 668 patent would not have been allowed" if the patent examiner had been aware of the '436 Patent or the '452 Patent.[101]

Neither of these purported reasons are supported by the facts. *First*, the FHT-1 was disclosed to the patent examiner via an Information Disclosure Statement that included a provisional patent application describing the FHT-1.[102]

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99 *Id.* at 1291.

100 Goldberg Report at 77-78.

101 *Id.* at 79.

102 *See* Excerpts from the '668 Patent File History, Ex. N to the Brown Decl., at 176.

Second, while the '452 Patent and the '436 Patent were not expressly disclosed to the patent examiner, both patents are listed on a search history initialed by the examiner.[103] Accordingly, Goldberg's opinions regarding inequitable conduct are unreliable and are therefore stricken.

6. Goldberg May Testify as to Non-Infringement

Medisim argues that Goldberg's refusal to consider 510(k) materials in reaching his non-infringement opinions reflects "a methodology that is arbitrary, unscientific, and unreliable."[104] This claim is without merit because Goldberg did not simply disregard the 510(k) materials. Instead, he explained at length why he considered them to be unreliable descriptions of the Accused Products, and why he believed it was inappropriate for Lipson to rely on them.[105]

Medisim's assertion that BestMed's brief on this point amounts to a "revisionist attempt to show that Goldberg's decision of [sic] the 510(k) documents is sensible" because "there was no Goldberg analysis of the K-Jump 510(k) documents"[106] is similarly incorrect. Goldberg clearly states that he considered the references listed in Exhibit B to his rebuttal report. As that list contains the 510(k)

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103 *See id.* at 207.

104 Medisim Mem. at 22.

105 *See* Goldberg Rebuttal Report at 17-20.

106 Medisim Rep. Mem. at 9.

materials, the charge that Goldberg ignored them is specious. That he declined to discuss them more thoroughly simply indicates that he believed the reasons already noted above to be sufficient. Medisim may disagree with his explanation, but its argument that Goldberg's methods in this area are arbitrary is contrary to fact.

Medisim next argues that Goldberg "stumbles when it comes to applying the Court's claim construction" in his enablement analysis.[107] Primarily, Medisim complains of Goldberg's opinion that oral temperatures are not acceptable estimates of core body temperature.[108] This complaint lacks merit.

Togawa, whom Goldberg expressly cites, clearly states that oral temperatures are "about 0.4 C below simultaneously measured mean pulmonary arterial temperature[s]."[109] Next, Goldberg cites a thermometry-industry standard which states that an estimated measurement that varies from its actual target by 0.4 degrees Celsius or more is considered unacceptable in the field.[110] Put together, these two citations support Goldberg's opinion that "conflating oral equivalent temperature with core body temperature under the assertion that oral equivalent

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[107] Medisim Mem. at 24.

[108] *See* Goldberg Rebuttal Report at 22.

[109] Tatsuo Togawa, *Body Temperature Measurement*, 6 Clin. Phys. Physiol. Meas. 83, 91 (1985).

[110] *See* Medisim Rep. Mem. at 10.

temperature is an approximation of core body temperature is contrary to any understanding in the field."[111] Accordingly, Goldberg's opinion that oral temperatures are not acceptable estimates of core body temperatures is not an *ipse dixit* conclusion, but an application of his expertise to claim terms as construed in the *Markman* Order. For these reasons, his non-infringement opinions are not stricken.

B. BestMed's Motion to Exclude

BestMed seeks to exclude those portions of the Lipson Report that it claims are contrary to this Court's *Markman* Order, based on unreliable science, or contrary to law.[112] BestMed also argues that the portions of the Lipson Report explaining K-Jump's 510(k) submissions should be stricken, as such materials do not need expert explanation.[113] Finally, it seeks to exclude the Keegan Report in its entirety.[114]

1. Lipson May Not Testify that the KD-2201 Meets the Deep Tissue Temperature Limitation of the '668 Patent

BestMed argues that Lipson's opinions on whether the accused

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111 *Id.* at 10 (quoting Goldberg Rebuttal Report at 22).

112 *See* BestMed Mem. at 2.

113 *See id.*

114 *See id.* at 17.

product meets the deep tissue temperature limitation of the '668 Patent should be excluded for three reasons. *First*, it argues that he disregarded the stipulated meaning of that term. *Second*, it argues that Lipson's construction of the term is incorrect. *Third*, it argues that his tests are based on junk science.[115] Even if the first and third arguments are decided in Medisim's favor, Lipson's opinion that the accused product meets the deep tissue temperature limitation of the '668 Patent is excluded for the reasons given below.

BestMed argues that Lipson's conclusion that the KD-2201 – one of the allegedly infringing thermometers – measures deep tissue temperature when used in test mode and allowed to reach thermo-equilibrium is "simply nonsensical."[116] This is so, according to BestMed, because a temperature measured at the skin's surface – even in the way Lipson describes – will never reach the temperature of the blood in the underlying temporal artery due to body tissue insulation and environmental conditions. Because Lipson expressly disagrees with that proposition, BestMed argues that his report is "contrary to the laws of physics and clearly wrong" and therefore "frivolous."[117]

Medisim responds in several ways. *First*, it notes that because the

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115 *See* BestMed. Mem. at 3-6.

116 *Id.* at 4.

117 *Id.* at 5-6.

KD-2201 has an insulating rubber hood, "the equilibrium temperature is not the same as a person's external skin temperature that is in equilibrium with the air temperature."[118] *Second*, it argues that BestMed's own expert "acknowledges that the maximum temperature of a probe in contact with a body site 'represents the deep tissue temperature claimed in the '668 patent.'"[119] *Third*, it argues that K-Jump's 510(k) submissions support Lipson's conclusion.[120]

A review of the scientific literature that underlies this dispute shows that neither Medisim nor BestMed is entirely correct. According to both Sessler and the Yamakage/Namiki team, a conductive thermometer implementing the "zero-heat-flux" method developed by Fox and Solman would indeed measure the temperature under the skin, to a depth of approximately one centimeter.[121] Accordingly, by arguing that there is a method by which it is possible to measure deep tissue temperature at the skin surface, Lipson is not saying anything that is facially impossible.

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[118] Medisim Opp. Mem. at 5.

[119] *Id.* at 6.

[120] *See id.*

[121] Michiaki Yamakage & Akiyoshi Namiki, *Deep Temperature Monitoring Using a Zero-Heat-Flow Method*, 17 J. Anesthesia 108, 111 (2003); Daniel I. Sessler, *Temperature Monitoring and Perioperative Thermoregulation*, 109 Anesthesiology 318, 319 (2008).

However, Lipson's implicit conclusion that it is possible to measure deep tissue temperature by allowing the KD-2201 to reach thermo-equilibrium is nonetheless incorrect.[122] This is so because that device does not make use of the zero-heat-flux method. Sessler, on whom Lipson relies, clearly indicates that implementing that method requires the use of two thermistors and a heating element to achieve the condition in which the temperature measured by the thermistor in contact with the skin is the equivalent of deep tissue temperature.[123] The Yamakage/Namiki team – on whom Goldberg relies to rebut Lipson – concurs.[124] Furthermore, Lipson himself states that the KD-2201 had only one thermistor and never mentions that the device has a heating element.[125] He also fails to show that the KD-2201 is capable of measuring deep tissue temperature at the skin surface in some other way.

Medisim argues that all of the forgoing merely establishes that there is "a factual issue on which experts reach difference [sic] conclusions," and that such

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[122] *See* Medisim Opp. Mem. at 4.

[123] Sessler, *supra* note 119, at 319.

[124] *See* Yamakage & Namiki, *supra* note 119, at 108. As Goldberg plainly relies on this article for the proposition that "the maximum temperature of a probe in contact with a body site 'represents the deep tissue temperature claimed in the '668 patent,'" Medisim's assertion that Goldberg agrees with Lipson is incorrect. *See* Medisim Opp. Mem. at 6.

[125] *See* Lipson Report at 15.

a disagreement does not merit striking Lipson's opinion as unreliable under *Daubert* and Rule 702.[126] Far from being a "logical conclusion"[127] or mere factual dispute, however, Lipson's determination that the KD-2201 measures deep tissue temperature at the skin surface is an unsupported *ipse dixit* conclusion, the acceptance of which is tantamount to an abdication of the court's role as gatekeeper of expert testimony.[128] Accordingly, Lipson may not testify that the KD-2201 meets the deep tissue temperature limitation of the '668 Patent.

2. Lipson May Testify that the KD-2201 Meets the Core Body Temperature Limitation of the '668 Patent

BestMed next argues that Lipson's opinion that the KD-2201 meets the "calculate a core body temperature" limitation of the '668 Patent must be excluded for two reasons: (1) that Lipson's use of that term is inconsistent with the *Markman* Order, and (2) that Lipson's testing methodology was flawed.[129]

a. Lipson Followed the *Markman* Order's Construction of "Calculate" and "Core Body Temperature"

At the *Markman* hearing, Medisim argued that peripheral

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126 *See* Medisim Opp. Mem. at 6.

127 *Id.* at 4.

128 *See Pension Comm. of Univ. of Montreal v. Banc of Am. Sec., LLC*, 691 F. Supp. 2d 448, 481 n.211(S.D.N.Y. 2010) (quoting *Vuitton IV*, 525 F. Supp. 2d at 643).

129 *See* BestMed Mem. at 8.

temperatures were core body temperatures. Lipson now argues that readings of oral temperatures "cluster more tightly around the pulmonary artery temperature than other peripheral temperatures,"and that oral temperatures are consequently viewed in the field as acceptable estimates of core body temperature.[130] Accordingly, he argues that even though an oral temperature is not a core body temperature, measuring an oral temperature necessarily "calculates" – that is, uses a "computation to estimate, approximate, predict or determine" – a core body temperature. Based on this understanding, Lipson then concludes that the KD-2201 calculates a core body temperature.[131]

The parties do not dispute that core body temperature can be "calculated" directly by inserting a catheter with a thermistor into the pulmonary artery. However, the *Markman* Order makes clear that a reliable estimation or approximation of the temperature of blood in the pulmonary artery is also a "calculation" of core body temperature.[132] While BestMed may attack the assertion that measurements of oral temperatures approximate core body temperatures, Lipson did not equate the two. Instead, he applied the *Markman* Order's

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[130] Lipson Report at 8.

[131] *See id*. at 30.

[132] *See Medisim Ltd. v. BestMed LLC*, 10 Civ. 2463, 2011 WL 2693896, at *10 (S.D.N.Y. July 8, 2011).

construction of the terms "calculate" and "core body temperature" to his understanding of the relationship between oral temperatures and core body temperatures. Accordingly, Lipson may testify to his opinion that the KD-2201 calculates a core body temperature.

b. Lipson's Testing Methodology Is Not Flawed

BestMed argues that Lipson misused the KD-192 – an admittedly non-infringing K-Jump thermometer – by drinking hot or cold liquids before using it to take temperatures.[133] The results of that "misuse" show that oral temperatures are noticeably affected by the consumption of such liquids when measured directly by thermometers like the KD-192.[134] By contrast, the temperature taken by the KD-2201 was not affected by the ingestion of hot or cold liquids. Accordingly, Lipson concluded that the KD-2201 displayed something other than direct oral temperature.[135] It was to illustrate this point that Lipson "misused" the KD-192,[136] and taken in that context, there was nothing inappropriate about him doing so.

BestMed also complains that Lipson's conclusion that the KD-2201 corrects from "test mode" readings to "normal mode" readings by use of an

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133 *See* BestMed Mem. at 11.

134 *See* Lipson Report at 20.

135 *See* Medisim Opp. Mem. at 12.

136 *See* Lipson Declaration at ¶ 5.

algorithm is unreliable for two reasons: (1) that the "test mode" reading cannot be a first step in obtaining the "normal mode" reading, because the former takes several minutes, while the latter takes only seconds, and (2) that Lipson completely failed to analyze the underlying source code controlling both modes.[137]

Lipson did not say that the KD-2201 first takes a "test mode" temperature and then uses it to calculate a "normal mode" temperature. Instead, he stated that the "normal mode" temperature is several degrees higher than the "test mode" temperature.[138] Furthermore, there is no doubt that he considered the source code.[139] Accordingly, both of these arguments are unavailing, and do not merit striking this portion of Lipson's report.[140]

3. Lipson's Analysis of 510(k) Materials Is Appropriate

BestMed asserts that Lipson's analysis of K-Jump's 510(k) submissions should be excluded under Rule 702 because "[t]here is no specialized

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[137] *See* BestMed Mem. at 12-13.

[138] *See* Lipson Report at 23.

[139] *See id.* at 18.

[140] BestMed also complains that Lipson's water bath tests are flawed because he equates the temperature of the water bath to deep tissue temperature without any support. *See* BestMed Mem. at 12. This argument is without merit, as Lipson clearly explains his reasoning for doing so; namely, that the water bath was the only source of heat to the thermometers tested, just as deep tissue temperature is the only source of heat for temperatures measured at the skin. *See* Lipson Declaration at ¶ 4.

knowledge necessary to read a 510(k)."[141] Having reviewed the 510(k) materials provided on this motion, I agree with Medisim that such materials are highly technical in nature, and find Lipson's use of such materials in reaching his opinions was appropriate.[142]

4. Lipson's Rebuttal Report Applies the Relevant Law

BestMed argues that portions of Lipson's rebuttal report should be stricken because he ignored the relevant law of enablement.[143] Specifically, BestMed complains that Lipson "neglects to cite any part of the '668 Patent specification," and that the materials he does cite should not be considered in an enablement analysis.[144]

As noted above, the patent specification must teach one skilled in the art how to practice the claimed invention. A corollary to this rule, also noted above, is that the specification need not disclose minor details that would be known to such a person. Lipson acknowledges these rules in his report.[145] Thus, BestMed's real complaint is that Lipson reached a different conclusion than its

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141 *See* BestMed Mem. at 14.

142 *See* Medisim Opp. Mem. at 14.

143 *See* BestMed Mem. at 14.

144 *See id.* at 16.

145 *See* Lipson Rebuttal Report at 12-13.

own expert.

It is equally clear that the materials Lipson considered were appropriate. While it is true that the patent specification is viewed as it stood on the date of filing for purposes of an enablement analysis,[146] an expert need not limit himself to the patent specification to assess the state of the art at that time. Accordingly, the fact that Lipson's complained-of citations were not incorporated into the patent specification by reference at the time of filing is irrelevant.[147] All of those documents pre-date the '668 Patent and were therefore appropriate matter to consider when assessing the state of the art at the time of filing.[148] For all these reasons, Lipson's rebuttal report will not be stricken for failure to apply the relevant law of enablement.

5. The Keegan Report Is Excluded

BestMed claims that the Keegan Report should be excluded under Rules 702 and 403 because it is flawed in two major ways: (1) Keegan used an

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[146] *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).

[147] Specifically, BestMed complains that Lipson cites to three patents issued to Weiss, Gregory, and Seifert. *See* BestMed Mem. at 15.

[148] BestMed also complains that Lipson again mis-uses the terms "deep tissue temperature" and "core body temperature." *See* BestMed Mem. at 16. As his "deep tissue temperature" opinions in his rebuttal report are the same as those in his initial report, they are excluded for the same reasons.

improper respondent universe, and (2) Keegan used an improper control product.[149]

a. Keegan's Respondent Universe Was Improper

When analyzing a claim under the Lanham Act, a court must consider "whether defendant's use of [a mark entitled to protection] is likely to cause consumers confusion as to the origin or sponsorship of the defendant's goods."[150]

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[149] BestMed also claims that Keegan biased the respondent pool by instructing them that "there is often a relationship between a retail store and its source manufacturers." BestMed Mem. at 23. Medisim argues that Keegan merely "correct[ed] for the possibility that some respondents might have been unaware of the potential relationship between the retailer and manufacturer," and that doing so was an appropriate way to "control *against* improper bias." Medisim Opp. Mem. at 24-25 (emphasis in original).

The use of a control group is the gold standard for eliminating survey responses due to a respondent's pre-existing beliefs and other "background noise." Diamond on Survey Research at 399. A carefully crafted instruction may have a similar effect, albeit in a more subjective way. *See id.* at 397. However, where the same instruction is given to both the control group and the test group, its effect will necessarily be negated if the control functions appropriately, which Medisim states is the case here. *See* Medisim Opp. Mem. at 25. Accordingly, I am not convinced that the instruction improperly biased the survey results.

Finally, BestMed complains that Keegan's survey did not reflect actual marketplace conditions. *See* BestMed Mem. at 18. Because the other issues raised by BestMed are dispositive, I decline to reach this issue.

[150] *Virgin Enters.*, 335 F.3d at 146. *Accord Starbucks Corp.*, 588 F.3d at 114 ("To prevail on a trademark infringement and unfair competition claim under [section 32(1) or section 43(a) of the Act], in addition to demonstrating that the plaintiff's mark is protected, the plaintiff must prove that the defendant's use of the allegedly infringing mark would likely cause confusion as to the origin or sponsorship of the defendant's goods with plaintiff's goods."); *Vuitton II*, 454 F.3d at 115. As the Supreme Court has made clear, the same likelihood of confusion analysis applies regardless of the name given to the trademark claim – e.g. false designation of origin, infringement, or something else. *See Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 780 (1992).

There is a likelihood of consumer confusion if "numerous ordinary prudent purchasers are likely to be misled or confused as to the source of the product in question because of the entrance in the marketplace of defendant's mark.'"[151] Accordingly, a survey purporting to determine whether there is a likelihood of consumer confusion at the point of sale must survey potential purchasers.

As noted above, Keegan used screening questions to ensure that survey respondents were likely to shop at stores that sold thermometers made by the parties. However, he did nothing to ensure that his respondents were likely to purchase those products. According to BestMed, this failure means that Keegan surveyed the wrong universe of respondents, leading to results that are necessarily irrelevant to this case.[152]

Medisim argues that "a digital thermometer is not a major planned purchase . . . for which a survey could easily locate individuals who are 'in the

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[151] *Playtex Prods., Inc. v. Georgia-Pacific Corp.*, 390 F.3d 158, 161 (2d Cir. 2004) (quoting *Cadbury Beverages, Inc. v. Cott Corp.*, 73 F.3d 474, 477-78 (2d Cir. 1996)). *Accord Chambers v. Time Warner, Inc.*, 282 F.3d 147, 155 (2d Cir. 2002) ("Where there is a claim of consumer confusion [as] to the association of a product or service with another person's trademark, the central inquiry is whether it is likely that 'an appreciable number of ordinarily prudent purchasers' will be misled as to the source or sponsorship of the product or service in question." (quoting *EMI Catalogue P'ship v. Hill, Holiday, Conors, Cosmopulos, Inc.*, 228 F.3d 56, 61-62 (2d Cir. 2000))).

[152] *See* BestMed Mem. at 22.

market.'"[153] Because of this, Medisim believes that "a survey of those who had already used this type of product and shopped at relevant stores would be good candidates for a potential purchaser."[154] This argument is unavailing for several reasons. *First*, a party may not simply excuse itself from surveying the relevant universe of respondents because it is difficult to assemble an appropriate sample of that population. *Second*, as Keegan himself notes, "repeat purchasing [of digital thermometers] is relatively infrequent . . . ."[155] If one credits this statement and makes the reasonable assumption that digital thermometer users own their devices, the logical conclusion is that such persons are not likely to purchase a digital thermometer within a reasonable timeframe.

Without information as to when current digital thermometer users bought their device, there is no way to tell if their familiarity with digital thermometers is equivalent to that of a true potential purchaser. Keegan intimates that current users obtain sufficient product familiarity by dint of shopping at the stores that sell the relevant products. As BestMed notes, however, shoppers at

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153 Medisim Opp. Mem. at 23.

154 *Id.* at 23-24.

155 12/20/11 Declaration of Warren Keegan Submitted in Connection with Medisim's Opposition to BestMed's Motion to Exclude Certain Expert Reports at 1.

such stores are also exposed to thousands of unrelated products.[156] Amidst this deluge, there is no basis to equate the knowledge of a person admittedly not shopping for a given product with that of a potential purchaser.

Based on the forgoing, I conclude that Keegan failed to survey the proper universe of respondents. As Medisim correctly notes, methodological errors typically go to the evidentiary weight of a survey, rather than its admissibility. Nonetheless, as Professor McCarthy notes, the selection of the respondent universe is a "crucial step," because "even if the proper questions are asked in a proper manner, if the wrong [universe is surveyed], the results are likely to be irrelevant."[157]

b. Keegan's Control Design Was Flawed

BestMed raises two points in support of its argument that Keegan used an improper control: (1) the control product Keegan used "does not exist in the marketplace and shares few similarities with either the K-Jump-manufactured or the outdated Medisim-manufactured thermometers," [158] and (2) that because Keegan did not specify which features of the Medisim product's packaging he was

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156 *See* BestMed Rep. Mem. at 8.

157 6 McCarthy on Trademarks § 32:170 at 32-351.

158 BestMed Mem. at 20. For this reason, BestMed believes that any reported confusion "is clearly due to the differences in the stimuli in the Test and Control conditions." *Id.*

testing, it is impossible to tell what generated the reported confusion, thereby "rendering [Keegan's] analysis meaningless."[159]

While a party may seek protection for the "overall look" of a product under the auspices of the trade dress doctrine, it cannot thereby "dispense with an articulation of the specific elements which comprise its distinct dress."[160] If this were not so, there would be nothing to prevent trade dress law from "slipping into protection for an otherwise unprotectable style, theme, or idea . . . ."[161]

Keegan does not explain what elements of Medisim's packaging constitute a protectable trade dress. Instead, he simply alludes to the fact that BestMed's product "was so similar in design and packaging to the Medisim product that it would cause consumer confusion . . . ."[162] Rather than explaining this omission, Medisim's brief merely indicates that Keegan chose a control that shared "certain characteristics" with the test product.[163] These failures are deeply troubling, and indicative of a serious flaw in the design of Keegan's survey.

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159 *Id.* at 21.

160 *Landscape Forms, Inc. v. Columbia Cascade Co.*, 113 F.3d 373, 381 (2d Cir. 1997).

161 *Gucci America, Inc. v. Guess?, Inc.*, No. 09 Civ. 4373, 2011 WL 5825206, at *6 (S.D.N.Y. Nov. 16, 2011) (quotation marks and citations omitted).

162 Keegan Report at 7.

163 Medisim Opp. Mem. at 22.

Furthermore, I am unable to determine whether Keegan's control was appropriate without understanding the scope of the claimed protection.

d. Because of Its Flaws, the Keegan Report Is Excluded

While both of the flaws noted above are quite serious, neither of them would justify excluding Keegan's report if taken separately. Nonetheless, because each flaw goes to a fundamental element of the survey rather than an issue on the periphery, their combined impact is too significant to overlook under *Daubert* and Rule 702. Accordingly, the Keegan report is excluded in its entirety.[164]

V. CONCLUSION

For the reasons given above, both motions are granted in part and denied in part as follows:

1. Goldberg's inequitable conduct opinions are stricken, along with those portions of his anticipation analysis discussed above;
2. Lipson's opinion that the KD-2201 meets the deep tissue temperature limitation of the '668 Patent is stricken;
3. The Keegan Report is excluded in its entirety.

The Clerk of the Court is directed to close these motions (Docket Nos. 55 and 59).

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[164] Given these substantial flaws, the Keegan report may also be excluded under Rule 403, as any minimal probative value it might retain is substantially outweighed by the risk of unfair prejudice and misleading the jury.

SO ORDERED:

Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
March 6, 2012

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ADDENDUM 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDISIM LTD.,

Plaintiff,

- against -

BESTMED LLC,

Defendant.

MEMORANDUM OPINION AND ORDER

10 Civ. 2463 (SAS)

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

Medisim Ltd. ("Medisim") brings this action against BestMed LLC ("BestMed") for patent and copyright infringement, unfair competition, false designation of origin, false advertising, deceptive acts and practices, unfair competition, and unjust enrichment. On March 6, 2012, I issued an opinion on cross-motions to exclude various expert reports ("March Opinion"). Medisim now moves under Local Rule 6.3 for re-consideration of the March Opinion as it relates to its experts, Lipson and Keegan.[1] With the Court's permission, BestMed

[1] *See* Medisim's Memorandum of Law in Support of Its Motion for Reconsideration Pursuant to Local Rule 6.3 ("Medisim Mem.").

formally opposed the motion.[2] For the reasons stated below, the motion is denied in part and granted in part.

II. BACKGROUND

The background to this motion, including a description of the Lipson and Keegan Reports, is fully set forth in the March Opinion. I excluded that portion of the Lipson Report that discussed whether the KD-2201 meets the "deep tissue temperature" limitation of the '668 Patent as unreliable, and also barred him from testifying at trial on that subject.[3] I excluded the Keegan Report because Keegan used a flawed control and an improper respondent universe.[4]

III. LEGAL STANDARD FOR RECONSIDERATION

Motions for reconsideration are governed by Local Rule 6.3 and are committed to the sound discretion of the district court.[5] A motion for reconsideration is appropriate where "'the moving party can point to controlling

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[2] *See* BestMed's Opposition to Medisim's Motion for Reconsideration ("BestMed Mem.").

[3] *See Medisim Ltd. v. BestMed, Inc.*, No. 10 Civ. 2463, 2012 WL 718041, at * 11 (S.D.N.Y. March 7, 2012) ("March Opinion").

[4] *See id.* at *15.

[5] *See Patterson v. United States*, No. 04 Civ. 3140, 2006 WL 2067036, at *1 (S.D.N.Y. July 26, 2006) ("The decision to grant or deny a motion for reconsideration is within the sound discretion of the district court.") (citing *McCarthy v. Manson*, 714 F.2d 234, 237 (2d Cir. 1983)).

decisions or data that the court overlooked – matters, in other words, that might reasonably be expected to alter the conclusion reached by the court.'"[6] A motion for reconsideration may also be granted to "'correct a clear error or prevent manifest injustice.'"[7]

The purpose of Local Rule 6.3 is to "'ensure the finality of decisions and to prevent the practice of a losing party examining a decision and then plugging the gaps of a lost motion with additional matters.'"[8] Local Rule 6.3 must be "narrowly construed and strictly applied so as to avoid repetitive arguments on issues that have been considered fully by the Court."[9] Courts have repeatedly been forced to warn counsel that such motions should not be made reflexively, to reargue "'those issues already considered when a party does not like the way the

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[6] *In re BDC 56 LLC*, 330 F.3d 111, 123 (2d Cir. 2003) (quoting *Shrader v. CSX Transp., Inc.*, 70 F.3d 255, 257 (2d Cir. 1995)), *abrogated on other grounds by In re Zarnel*, 619 F.3d 156 (2d Cir. 2010).

[7] *RST (2005) Inc. v. Research in Motion Ltd.*, No. 07 Civ. 3737, 2009 WL 274467, at *1 (S.D.N.Y. Feb. 4, 2009) (quoting *Virgin Atl. Airways, Ltd. v. National Mediation Bd.*, 956 F.2d 1245, 1255 (2d Cir. 1992)).

[8] *Grand Crossing, L.P. v. United States Underwriters Ins. Co.*, No. 03 Civ. 5429, 2008 WL 4525400, at *3 (S.D.N.Y. Oct. 6, 2008) (quoting *SEC v. Ashbury Capital Partners*, No. 00 Civ. 7898, 2001 WL 604044, at *1 (S.D.N.Y. May 31, 2001).

[9] *United States v. Treacy*, No. 08 Cr. 0366, 2009 WL 47496, at *1 (S.D.N.Y. Jan. 8, 2009) (quotation omitted).

original motion was resolved.'"[10] A motion for reconsideration is not an "opportunity for making new arguments that could have been previously advanced,"[11] nor is it a substitute for appeal.[12]

IV. DISCUSSION

A. Lipson May Testify as to "Deep Tissue Temperature" Insofar as He Does Not Rely on His Flawed Empirical Testing

In the March Opinion, I concluded – based on the arguments of the parties and the scientific literature reviewed by the experts – that it is impossible to measure "deep tissue temperature" – as that term was construed in the *Markman* Opinion – without using the zero-heat-flux method. Because of this conclusion, I held that Lipson would not be allowed to testify that the Accused Products met the "deep tissue temperature" limitation of the '668 Patent.[13]

Medisim argues that this holding was flawed in two ways. *First*, it argues that I misread the scientific literature, and that it is indeed possible to

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[10] *Makas v. Orlando*, No. 06 Civ. 14305, 2008 WL 2139131, at *1 (S.D.N.Y. May 19, 2008) (quoting *In re Houbigant, Inc.*, 914 F. Supp. 997, 1001 (S.D.N.Y. 1996)).

[11] *Associated Press v. United States Dep't of Defense*, 395 F. Supp. 2d 17, 19 (S.D.N.Y. 2005).

[12] *See Grand Crossing, L.P. v. United States Underwriters Ins. Co.*, No. 03 Civ. 5429, 2008 WL 4525400 (S.D.N.Y. Oct. 6, 2008).

[13] *See* March Opinion, 2012 WL 718041, at *11-12.

measure "deep tissue temperature" without the zero-heat-flux method, as indicated by Lipson's empirical testing of the KD-2201 in "test mode." *Second*, it argues that my exclusion of Lipson's "deep tissue temperature" opinions was overly broad, as the flaws identified in the March Opinion only relate to a portion of his testimony on the subject.[14]

Medisim's first argument is rejected for three reasons. *First*, Medisim does not point to new evidence, or evidence that this Court overlooked. *Second*, Medisim does not argue that this facet of the March Opinion results in manifest injustice. *Third*, and most importantly, it does nothing more than register the belief that the March Opinion was incorrect as a technical matter. Such an argument is a matter for appeal, not reconsideration.[15] Accordingly, Lipson may not testify that

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[14] *See* Medisim Mem. at 2-5.

[15] Moreover, Medisim's argument that the March Opinion was technically incorrect is unpersuasive on the merits. The core of its argument is that Sessler and Yamakage/Namiki used different terminology than the '668 Patent, and were therefore wrongly applied to this case. *See id*. at 3-4. The parties agreed at the *Markman* hearing to use the claim language itself, which defines deep tissue temperature as the temperature of the body "at a location under the skin that is a source of heat conducted to the one or more temperature sensors." *See* 4/28/11 Tr. at 108:17-109:16. In the March Opinion, I concluded that the scientific literature upon which Lipson relied indicates that the zero-heat-flux method allows measurement to a depth of approximately one centimeter, making it possible to measure the temperature in blood vessels near the skin's surface. Because these blood vessels are the source of heat to a temperature sensor resting on the skin, it is therefore possible to measure "deep tissue temperature" using the zero-heat-flux method. *See* March Opinion, 2012 WL 718041, at *11. What Sessler and Yamakage/Namiki actually describe – as opposed to the terms they use to describe

the KD-2201 meets the "deep tissue temperature" limitation of the '668 Patent based on his empirical testing of that product in "test mode."

Medisim next argues that the March Opinion overlooked the possibility that Lipson's "deep tissue temperature" opinions might find independent support in the 510(k) letters – including an American Society for Testing and Materials ("ATSM") standard referenced therein – and deposition testimony of K-Jump witnesses referenced in his report. Accordingly, it asserts that Lipson should be allowed to give his "deep tissue temperature" opinions based on those materials ("Reconsideration Materials").[16]

As explained in the March Opinion, I have serious doubts regarding whether Lipson's "deep tissue temperature" opinions are correct. On the strength of those concerns, I found that Lipson's opinions on the subject was a mere *ipse dixit*, and that accepting it as reliable would therefore violate my duty as a gatekeeper. Because of my focus on that issue, I did not give adequate consideration to the Reconsideration Materials – which were more heavily referenced in Lipson's claim chart than in the main text of his report – in the March Opinion.

The Reconsideration Materials – all of which come from K-Jump

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it – is fully consistent with this view.

[16] *See* Medisim Mem. at 4-5.

sources – are independent of Lipson's flawed empirical testing. Having now reviewed them more fully, I find that they provide a sufficiently sound basis for Lipson's opinion that the KD-2201 meets the "deep tissue temperature" limitation of the '668 Patent. Because the Federal Rules of Evidence – and the case law in this Circuit – favor the admissibility of expert testimony and because courts should focus on an expert's methodology rather than his ultimate conclusions, this finding now leads me to conclude that Lipson may testify that the KD-2201 meets the "deep tissue temperature" limitation of the '668 Patent. Accordingly, I now hold that he may give such testimony, insofar as it is based on the Reconsideration Materials.

B. The Keegan Report Remains Excluded

Medisim argues that, with respect to the Keegan Report, the March Opinion is flawed in two ways. *First*, it argues that I misunderstood the reasons why Dr. Keegan selected his respondent universe, and that his selection was not flawed. *Second*, it argues that I failed to consider whether the Keegan Report was admissible evidence on its state law claims.[17]

1. Medisim's Arguments Regarding Keegan's Respondent Universe Are Not Grounds for Reconsideration

Medisim's argument that Keegan correctly chose his respondent

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[17] *See* Medsim Mem. at 6-10.

universe – surveying *users* of digital thermometers instead of *potential purchasers* – is substantially the same as that which it made in response to BestMed's original motion to exclude Keegan's report. Although Medisim now fleshes out its argument on this point in response to the March Opinion, it points to nothing that could reasonably be expected to alter the conclusion reached therein. The Court fully understood the import of the argument, and rejected it for all of the reasons noted in the March Opinion.[18] Accordingly, the conclusion that the Keegan Report is flawed in this regard stands, and Medisim's first ground for reconsideration is rejected.

2. The Argument that the Keegan Survey Should Have Been Admitted on Certain State Law Claims Is Untimely

In the original *Daubert* submissions, the parties focused the Court's attention on the admissibility of the Keegan Survey with respect to Medisim's Lanham Act claims. Medisim now argues at length that even if the Keegan Survey was properly excluded on its Lanham Act claims, it should be admitted as relevant evidence on its claims under sections 349 and 350 of New York's General Business Law, as well as common law unfair competition.[19] These arguments are untimely. Medisim was free to argue that the Keegan Survey should be admitted

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[18] *See* March Opinion, 2012 WL 718041, at *13-14.

[19] *See* Medisim Mem. at 8-10.

solely as to its state law claims, but did not do so. Instead, Medisim chose to focus this Court's attention on those sections of its Complaint relating solely to *federal* patent, copyright, and trademark laws.[20]

Regardless of *why* it made the arguments it did in the underlying motion papers, there is no doubt that the theory of admissibility Medisim now posits is raised for the first time on this motion. It would be difficult to conceive of a clearer example of "a losing party examining a decision and then plugging the gaps of a lost motion with additional matters." Accordingly, this argument for reconsideration is also rejected.[21]

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[20] *See* Medisim's Memorandum of Law in Opposition to BestMed's Motion to Strike Portions of Plaintiff's Experts, Lipson and Keegan, at 19. Indeed, that argument would raise entirely new issues under Federal Rule of Evidence 403, as the probative value of the Keegan Survey on the state law claims might well be outweighed by the danger of confusing the issues before the jury.

[21] Furthermore, this new limited-admissibility theory may be without merit. As other courts in this district have explained, "[i]t is well settled that . . . trademark or trade dress infringement claims are not cognizable under [sections 349 and 350 of New York's General Business Law] unless there is a specific and substantial injury to the public interest over and above ordinary trademark infringement or dilution." *See, e.g., National Distillers Prods. Co., LLC v. Refreshment Brands, Inc.*, 198 F. Supp. 2d 474, 486-87 (S.D.N.Y. 2002). Likewise, the Second Circuit has stated that trademark or trade dress claims brought under the guise of the New York common law of unfair competition have identical requirements as Lanham Act unfair competition claims, except that the former requires an additional showing of bad faith or intent. *See Nadel v. Play-By-Play Toys & Novelties, Inc.*, 208 F.3d 368, 383 (2d Cir. 2000). *See also U.S. Polo Ass'n, Inc. v. PRL USA Holdings, Inc.*, 800 F. Supp. 2d 515, 538 (S.D.N.Y. 2011). It stands to reason that if a survey is so flawed as to require exclusion on Lanham Act claims, it cannot support claims that require additional

V. CONCLUSION

For the reasons noted above, BestMed's motion to reconsider is granted in part and denied in part as follows:

1) Lipson may testify that the KD-2201 meets the "deep tissue temperature" limitation of the '668 Patent based on his understanding of the Reconsideration Materials;

2) The Keegan Survey remains excluded in its entirety.

The Clerk of the Court is directed to close this motion (Docket No. 76).

SO ORDERED:

Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
April 23, 2012

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showings *beyond* those of the Lanham Act.

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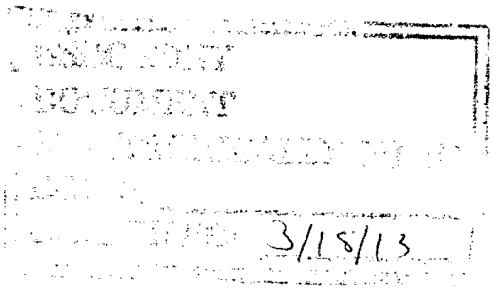
ADDENDUM 3



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDISIM, LTD,

Plaintiff,

- against -

BESTMED, LLC,

Defendant.

ORDER

10 Civ. 2463 (SAS)

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. Summary of Letters

A. Medisim's Letter

Medisim's March 11, 2013 letter to the Court ("Medisim Ltr.") requests that the Court strike BestMed's Federal Rule of Civil Procedure ("Rule") 50(b) motion regarding the validity of the '353 patent, on the grounds that it was not properly preserved through a pre-verdict Rule 50(a) motion.[1] Alternatively, Medisim seeks leave to file a motion to strike on March 18, 2013, in conjunction with its opposition to BestMed's pending motion for Judgment as a Matter of Law ("JMOL"), and requests a briefing schedule in connection with this proposed motion.[2]

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[1] *See* Medisim Ltr. at 1.

[2] *See id.* at 3.

The crux of Medisim's argument is that BestMed failed to present its specific invalidity theories until after the verdict, thereby depriving Medisim of the chance to contest them at trial.[3] Specifically, Medisim alleges that BestMed did not move for judgment as a matter of law on validity under Rule 50(a) prior to the verdict,[4] and argues that BestMed is therefore barred from now moving under Rule 50(b) on the grounds of patent invalidity for anticipation, obviousness, enablement, and deficient written description.[5] In support of this argument, Medisim cites binding authority that "a party must file a pre-verdict JMOL motion on all theories, and with respect to all prior art references, that it wishes to challenge with a post-verdict JMOL."[6]

B. BestMed's Letter

In its response letter dated March 14, 2013 ("BestMed Ltr."), BestMed contends that Medisim's reading of Rule 50 is "pedantic."[7] It points out that, when BestMed attempted to re-assert its previous motions prior to the verdict,

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[3] *See id.*

[4] *See id.* at 1 n.1 (citing 2/6/13 Trial Transcript ("Tr.") at 1205-1240).

[5] *See id.* at 1 & n.2.

[6] *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 845 (Fed. Cir. 2010). *See* Medisim Ltr. at 2 (citations omitted).

[7] BestMed Ltr. at 1.

the Court stated that "'you [have] preserved the record, [and] renewed all the motions previously made[.]'"[8] Additionally, BestMed alleges that it stated the basis for its current JMOL during the JMOL conference,[9] and argues that as a result, Medisim is not prejudiced by its present Rule 50(b) motion. BestMed then cites to substantial authority, from the Federal Circuit as well as the Second Circuit, standing for the proposition that, because the purpose of a pre-verdict motion under Rule 50(a) is to alert the court to the party's legal position and to put the opposing party on notice of the moving party's position as to the insufficiency of the evidence, BestMed's post-trial JMOL on validity was properly preserved.[10]

II. RULING

Medisim's argument that it has been unfairly surprised by BestMed's current contentions is not supported by the evidence. As BestMed's letter points out, it has asserted its present invalidity contentions on the record, and the Court has stated that all of its contentions had been re-asserted and preserved. These

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[8] *Id.* at 2 (quoting 2/7/13 Tr. at 1495:24-25).

[9] *See id.* at 2-3 (citing 2/8/13 Tr. at 1625:17-1626:11; 1626:13-22; 1626:24-1627:7; 1627:8-12).

[10] *See id.* at 2 (citing, *e.g.*, *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974-74 (Fed. Cir. 2010) (holding that right to bring post-trial JMOL on invalidity was preserved when, under the circumstances, "neither [the plaintiff] nor the district judge could have failed to understand [defendant's] position")).

facts are therefore distinguishable from *i4i Ltd. Partnership v. Microsoft Corp.*, in which the Federal Circuit held that defendant's pre-verdict JMOL on anticipation, based on certain prior art, was insufficient to preserve its post-verdict JMOL on *obviousness*, based on *different* prior art.[11]

Moreover, the rule of *Duro-Last, Inc. v. Custom Seal, Inc.*,[12] which *i4i Partnership* applies, is based on the proposition that it would be impermissible under the Seventh Amendment to re-examine the jury's verdict upon grounds not raised prior to the verdict. Here, this rule is easily met: BestMed has pressed its invalidity contentions since well before the jury was sworn, the jury was instructed as to invalidity, and BestMed presented its present invalidity contentions, and its supporting evidence, on the record.

To preserve the right to file a Rule 50(b) motion, the movant must have "sought relief on similar grounds under Rule 50(a) before the case was submitted to the jury."[13] BestMed has done that here. Accordingly, Medisim's request to strike BestMed's Rule 50(b) JMOL regarding validity is denied. However, Medisim is free to preserve this argument in its forthcoming opposition

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[11] *See i4i Ltd. P'ship*, 598 F.3d at 845.

[12] 321 F.3d 1098 (Fed. Cir. 2003).

[13] *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486 n.5 (2008).

brief.

SO ORDERED:

Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
March 18, 2013

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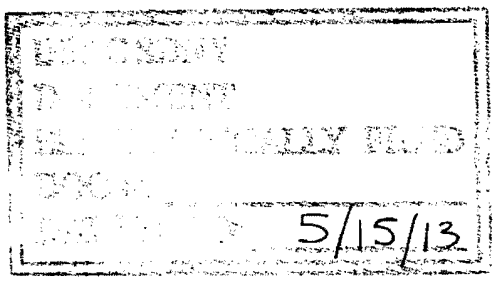
ADDENDUM 4



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDISIM LTD.,

Plaintiff,

- against -

BESTMED LLC,

Defendant.

OPINION AND ORDER

10 Civ. 2463 (SAS)

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

This is an action for the infringement of a patent for a non-invasive thermometer. The case was tried to a jury, which returned a verdict finding that defendant BestMed LLC ("BestMed") willfully infringed on U.S. Patent No. 7,597,668 ("the '668 Patent"), of which plaintiff Medisim Ltd. ("Medisim") is the sole assignee and owner. The jury also found that BestMed infringed Medisim's copyright in the Instructions for Use ("IFU") for its thermometers, and that BestMed was unjustly enriched under New York law. The jury awarded Medisim $1.2 million for its patent infringement claim, and $2.29 million for its unjust enrichment claim. Medisim sought only equitable relief for its copyright claim.

Presently before the Court is BestMed's post-trial motion for judgment as a matter of law ("JMOL"), or, alternatively, for a new trial. BestMed asserts the following grounds in support of its motion: (1) the '668 Patent is invalid (on four theories); (2) BestMed did not infringe on the '668 Patent, directly or indirectly; (3) there was insufficient evidence of willful infringement; (4) BestMed is not liable for unjust enrichment under New York law; and (5) Medisim is not entitled to damages. Also pending are three motions brought by Medisim, seeking, respectively, a permanent injunction and disposition of infringing materials, post-trial relief, and a judicial finding of willful infringement.

Although this case was expansive when opening arguments began, it narrowed substantially prior to the jury's deliberations. Specifically, the evidence presented at trial narrowed the anticipation inquiry to the question of whether the prior art FHT-1 thermometer meets the 'deep tissue temperature' limitation of the '668 Patent. The jury's verdict of no anticipation implicitly answered this question in the negative. However, the evidence presented at trial clearly and convincingly demonstrates that the FHT-1 calculates 'deep tissue temperature,' and no reasonable jury could have found otherwise. Therefore, BestMed's motion for JMOL on anticipation is granted.

Similarly, Medisim's claim for unjust enrichment was narrowed

substantially prior to its submission to the jury. Because substantial evidence does not support the jury's verdict awarding damages to Medisim for unjust enrichment, JMOL on unjust enrichment is granted. Finally, Medisim's pending motions are denied, save for its motion for an injunction disposing of materials infringing its copyright, which is granted.

II. BACKGROUND[1]

BestMed's motion for a JMOL of invalidity and non-infringement turns entirely on an exceedingly narrow issue: whether the FHT-1 thermometer, a non-invasive temple thermometer sold by Medisim more than one year prior to the effective date of the '668 Patent, meets the deep tissue temperature limitation of the '668 Patent.[2] When placed in its proper context, it is plain that this issue must be resolved in BestMed's favor.

Providing the proper context is a difficult undertaking in light of this

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[1] The facts of this case have been recited in numerous opinions over the course of this litigation. *See, e.g., Medisim Ltd. v. BestMed LLC* (the "S.J. Op."), No. 10 Civ. 2463, – F. Supp. 2d –, 2012 WL 5954757, at *1 (S.D.N.Y. Nov. 28, 2012) (ruling on the parties' cross motions for summary judgment). Familiarity with these prior opinions is assumed.

[2] "FHT" means "forehead thermometer," and the designation refers to Medisim's line of non-invasive (or semi-invasive, *e.g.*, armpit) thermometers. *See* Trial Transcript ("Tr.") (Direct Examination of Moshe Yarden ("Yarden Direct")) at 106:9. Medisim also had a line of invasive thermometers, which are designated M5T. *See id*. (Cross-Examination of Stanley Cohen ("Cohen Cross")) at 745:14-19.

case's technical complexity, thorny procedural history, and voluminous trial record. Moreover, when considering a post-trial motion for JMOL, a court must take the utmost care not to impinge upon the vital role of the jury in our judicial system. For these reasons, although the material question in this case is narrow and readily resolved, it is necessary to provide a detailed recitation of the facts relevant to validity and infringement.

The section below therefore recites a full account of the facts, beginning with the Court's claim construction, and ending with the evidence adduced at trial. It then summarizes the facts relevant to BestMed's motion to set aside the verdict of unjust enrichment.

A. Claim Construction

The '668 Patent was filed on May 31, 2006 and issued on October 6, 2009 to Moshe Yarden, one of Medisim's founding partners.[3] It incorporates by reference an earlier patent, U.S. Patent No. 6,280,397 ("the '397 Patent"), which was issued on August 28, 2001. The '397 Patent names Yarden as a co-inventor, and is also assigned to Medisim.[4]

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[3] *See* Stipulation of Undisputed Facts ("Stip. Facts"), Ex. A to Joint Pre-Trial Order, ¶¶ 2; 8.

[4] *See Medisim Ltd. v. BestMed LLC* (the "*Markman* Op."), No. 10 Civ. 2463, 2011 WL 2693896, at *1 (S.D.N.Y. July 8, 2011).

The '668 Patent is titled "Non-Invasive Temperature Measurement." As this title suggests, the claimed invention relates to a non-invasive thermometer. The '668 Patent contains two independent claims: an apparatus claim and a method claim. Claim 1, the independent *apparatus* claim, states:

> A thermometric device, comprising:
>
> a probe, comprising:
>
> a membrane configured to be applied to an external surface of a body of a subject; and
>
> one or more temperature sensors located within the probe in thermal contact with the membrane; and
>
> a processing unit configured to receive a plurality of temperature readings from the one or more temperature sensors, to determine time-dependent parameters of temperature change responsively to the plurality of temperature readings *to calculate, a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors*, and to calculate a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.[5]

In my *Markman* Order, I gave the following constructions to the disputed terms in Claim 1:

"Probe" means "portion of thermometer including a membrane

[5] '668 Patent at col. 10:1-18 (emphasis added to demarcate the "deep tissue temperature" limitation).

and one or more temperature sensors that touches the exterior skin."

"Membrane" means "a layer or sheet of material."

"One or more temperature sensors" means "one or more thermistor or resistance temperature defectors (RTDs), or any form of thermistor, temperature sensor, or thermocouple."

"Configured to receive a plurality of temperature readings from the one or more temperature sensors" means "configured to receive temperature readings, at least one of which comes from the external body surface, from one or more temperature sensors."

"Time-dependent parameters of temperature change," means "multiple values of temperature change that vary with time and that are taken at different times."

"To calculate" [means] "using a computation to estimate, approximate, predict or determine."

"Core body temperature" [means] "the temperature of blood in the pulmonary artery."[6]

The independent *method* claim of the '668 Patent, Claim 21, states:

A method for thermometric measurement, comprising:

> applying a probe, which comprises a heat-conducting membrane and one or more temperature sensors in thermal communication with the membrane, to an external surface of a body of a subject;
>
> receiving a plurality of temperature readings from the one or more temperature sensors while the probe is applied to

[6] *Markman* Op., 2011 WL 2693896, at *11 (quoting '668 Patent at col. 10:1-18).

> the surface of the body;
>
> determining time-dependent parameters of temperature change responsively to the plurality of temperature readings;
>
> calculating a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors; and calculating a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.[7]

My *Markman* order construed Claim 21 as follows: "the user is 'applying a probe . . . to an external surface,' while the processing unit is 'receiving a plurality of temperature readings'; 'determining time-dependent parameters of temperature change'; 'calculating a deep tissue temperature' and 'calculating a core body temperature.'"[8]

B. The Deep Tissue Temperature Limitation

The only dispute as to anticipation is whether the FHT-1 meets the deep tissue limitation of the '668 Patent.[9] This section sets forth the facts of record

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[7] '668 Patent at col. 11:25-41.

[8] *Markman* Op., 2011 WL 2693896, at *11 (quoting '668 Patent at col. 11:25-41).

[9] *See* BestMed's Memorandum in Support of Its Motion for JMOL or, Alternatively, for a New Trial ("Def. Mem.") at 2; Memorandum in Support of Medisim's Opposition to BestMed's Motion for JMOL, or, Alternatively for a New Trial ("Opp. Mem.") at 3-4.

relevant to this limitation, including: (1) the intrinsic evidence; (2) the procedural history; and (3) the evidence presented at trial.

1. Intrinsic Evidence

a. Claim Construction

i. "Deep Tissue Temperature"

Medisim advanced the following construction of "deep tissue temperature" in its *Markman* brief: "stable temperature under the skin that is minimally affected by external factors and is the source of heat conducted to the one or more sensors."[10] BestMed advanced the construction that "deep tissue temperature" means "a heat source below the skin."[11] At the *Markman* hearing, though, the parties agreed that the term did not need to be construed,[12] and I subsequently declined to construe it.[13]

The litigation therefore proceeded on the assumption that "deep tissue temperature" was to be given its plain and ordinary meaning in the context of the

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[10] 3/4/11 Plaintiff's Opening Claim Construction Brief, Doc. No. 33, at 15.

[11] 3/4/11 Opening Claim Construction Brief by BestMed ("Def. *Markman* Br."), Doc. No. 34, at 18.

[12] *See* 4/28/11 Hearing Transcript at 108:18-19.

[13] *See Markman* Op., 2011 WL 2693896, at *9.

intrinsic evidence.[14] There is no dispute that, in the '668 Patent, the term "deep tissue temperature" "reflects" the "temperature at a location under the skin that is the source of heat conducted to the sensors in the probe. . . ."[15]

Two points follow directly from this construction of "deep tissue temperature." *First*, plainly, the "source of heat" that causes the measured "temperature at a location under the skin" will vary depending upon where the probe is applied. For example, if the probe were applied to the temple, the source of heat would be the temporal artery, and the deep tissue temperature would therefore approximate this temperature. *Second*, "deep tissue temperature" (also called "local temperature" in the '668 Patent) is distinct from "surface temperature," *i.e.*, the temperature of the exterior skin, and from "core temperature," *i.e.* the temperature of the pulmonary artery.

ii. The Deep Tissue Temperature Limitation

During *Markman* proceedings, BestMed contended that the deep tissue temperature limitation — as opposed to the phrase "deep tissue temperature"

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[14] *See Biogen Idec, Inc. v. GlaxoSmithKline LLC*, No. 2012-1120, – F.3d –, 2013 WL 1603360, at *4 (Fed. Cir. Apr. 16, 2013) ("[A] term's ordinary meaning must be considered in the context of all the intrinsic evidence, including the claims, specification, and prosecution history.") (citations omitted).

[15] '668 Patent at col. 2:3-5. *See* Tr. (Medisim Summation) at 1617:20-22 ("And the parties agreed that local or deep tissue temperature is the temperature, the heat under the skin, that's not in dispute.").

in isolation — is a means-plus-function claim under Title 35 of the United States Code, Section 112, ¶ 6. Specifically, BestMed argued that although the limitation does not use the catch-word "means," it nevertheless employs means-plus-function claiming, because the only structure that the '668 Patent discloses is a generic "processing unit," and the only method it discloses for calculating a deep tissue temperature is the '397 algorithm.[16] Based on this argument, BestMed offered the following construction of the limitation: "[t]he microprocessor calculates the temperature of a heat source below the skin's surface according to the algorithm set forth in [the '397 Patent at col. 1:1-58-col. 2:1-57 (the "'397 algorithm")]."[17]

Because of the presumption against means-plus-function claiming created by the absence of the word "means," and because the specification of the '668 Patent disclosed sufficient structure, I did not construe the deep tissue temperature limitation as a means-plus-function claim.[18] This ruling resolved *sub silentio* BestMed's argument that the '668 Patent did not disclose sufficient

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[16] *See id*. at 19-21.

[17] Def. *Markman* Br. at 19.

[18] *See Markman* Op., 2011 WL 2693896, at *10 ("In light of the strong presumption against applying § 112, ¶ 6 and this claim language, I find that 'processing unit' connotes a sufficiently definite structure to a person of ordinary skill in the art to avoid § 112, ¶ 6 treatment.") (citing *Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 649 F.3d 1350, 1360 (Fed. Cir. 2011)).

structure to calculate a deep tissue temperature by any means other than through the '397 algorithm,[19] an argument properly addressed to enablement, not the analysis of means-plus-function claiming.

b. Deriving Deep Tissue Temperature

Although the parties agree on the construction of the term deep tissue temperature, they dispute how that temperature is derived. The intrinsic evidence sheds some light on this dispute. The '668 Patent indicates that deep tissue temperature may be derived from the heat-flux algorithm of the '397 Patent, and discloses an embodiment in which a two-sensor probe applied to an external body surface uses the output of the '397 Patent in conjunction with an empirically derived formula to determine the user's core body temperature. Moreover, the prosecution history of the '668 Patent estops Medisim from denying that a user's deep tissue temperature may be derived from an infrared thermometer applied to the user's forehead.

i. The '668 Patent

The '668 Patent states that "[t]he thermometer is configured to perform the heat flux calculation [*e.g.*, an algorithm similar, or identical, to that

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[19] Def. *Markman* Br. at 20 ("The '668 Patent teaches no algorithm for calculating deep tissue temperature, except vis-a-vis the '397 Patent . . . . Thus, the subject claim phrase is subject to §112, ¶ 6, and should be construed as limited to the '397 Patent algorithm.").

disclosed in the '397 Patent] so as to derive a value of the [] [deep tissue] temperature."[20] In particular, the '668 Patent discloses an embodiment in which,

> [u]sing the heat flux algorithm described in the . . . ['397 Patent], the processing unit calculates from the temperature readings a local temperature. The local temperature, also referred to as a deep tissue temperature, reflects a temperature at a location under the skin that is the source of heat conducted to the sensors in the probe.[21]

The '668 Patent teaches that a reliable approximation of core temperature may be derived from a measurement of the skin's surface temperature if this temperature is first converted to an approximation of deep tissue temperature. It states that:

> The local temperature determined by the '397 algorithm is less affected than the surface temperature at the measurement site is [by] external factors such as ambient temperature and humidity. The local temperature is also less subject to variations in the body's heat regulation at the body's extremities. Consequently, there is a closer correlation between local temperature and core body temperature than there is between surface temperature and core body temperature.[22]

The Appendix of the '668 Patent (the "Appendix") teaches that the '397 Patent "provides a method for rapidly determining a core body temperature based on heat flux through a thermometer when the thermometer is inserted into an

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[20] '668 Patent at col. 2:6-7.

[21] *Id*. at col. 6:55-62.

[22] *Id*. at col. 7:1-8.

orifice of the body."[23] The '668 Patent further states that "[t]he accuracy of the derived temperature of [the '397 patent] is diminished when temperature measurements are made at an external measurement site on the body[,]" and goes on to provide an embodiment of the claimed invention in which "an empirically derived formula is used by the processing unit to determine core body temperature based on temperature readings made by sensors within the probe when the probe is applied to an external body surface."[24]

It is necessary to summarize this formula in order to properly evaluate BestMed's anticipation contentions. The inputs to the formula are "temperature readings from two sensors: a first sensor positioned at a shorter thermal distance from the thermometer membrane, and a second sensor at a farther distance."[25] In the exemplary embodiment disclosed by the Appendix, these temperature readings are taken ten times at 0.4 seconds intervals.[26]

The formula comprises nine constants, each used only once, and six variables. It is the sum of nine terms: (1) one constant; (2-6) five variables, each of

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[23] *Id*. at col. 9:15-18.

[24] *Id*. at col. 9:15-27.

[25] *Id*. at col. 9:27-29.

[26] *See id*. at col. 9:47-52.

which is multiplied by a separate constant; and (7-9) one variable used three times, in third-order polynomial form, and multiplied by a separate constant in each of its three appearances.[27]

The nine constants are empirically derived. Five of the six variables used are: (1) the difference between the second and final temperature readings of the first sensor, *i.e.*, the sensor that is closer to the "layer or sheet of material" covering the probe and in thermal contact with the skin;[28] (2-3) the rate of change, in degrees per second, of the first and second sensors after five intervals; and (4-5) the readings of the first and second sensors after the final interval.[29]

The sixth variable used in the formula is "$T_{avg}[,]$" which is defined by the '668 Patent as "the heat-flux derived temperature of [the '397 Patent]."[30] The '397 Patent claims "[a] high speed accurate temperature measuring device

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[27] *See id*. at col. 9:34-36 (providing the equation "Core Body Temperature = $(C_5 \times T_{b10-2}) + (C_{rdot5} \times T_{rdot5}) + (C_{bdot5} \times T_{bdot5}) + (C_{r10} \times T_{r10}) + (C_{b10} \times T_{b10}) + (C_3 \times T_{avg}) + (C_4 \times (T_{avg}))^2 + (C_7 \times (T_{avg}))^3 + C_6$)").

[28] *Markman* Op., 2011 WL 2693896, at *11 (construing the term "membrane").

[29] *See* '668 Patent at col. 9:52-61.

[30] *Id*. at col. 9:62-63. The '397 Patent was introduced into evidence as Exhibit 48. *See* Tr. (Yarden Direct) at 100:24-101:1 (identifying exhibit as the '397 Patent).

especially useful[] for measuring human body temperature[,]"[31] and teaches an algorithm "whereby the body temperature is calculated according to heat flux [*i.e.*, the rate of heat energy transfer] measured (a) between the body and a first temperature sensor and (b) between the first temperature sensor and a second temperature sensor (or sensors)."[32] In essence, the '397 algorithm is a method of rapidly predicting the thermoequilibrium temperature of the human body by taking temperature measurements at known intervals with two or more parallel sensors, separated by a known distance, with an insulating material of known thermal conductivity interposed between them, and with one sensor in thermal contact with the body (either directly or by being in thermal contact with a membrane that is in thermal contact with the body).[33]

The specification of the '668 Patent refers to variables (1-3) of the formula disclosed in the Appendix as "time dependent parameters of temperature change," and, unsurprisingly, refers to variables (4-5) as merely "temperature

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[31] '397 Patent at col. 5:46-47. The '397 Patent does not mention core body temperature or deep tissue temperature, and appears to have been intended for invasive use. *See id*. at col. 6:1-2 (Claim 1) (claiming "an elongated temperature probe with a rounded insertion tip for insertion into a body cavity").

[32] *Id*. at col. 1:46-49. *See* Tr. (Yarden Direct) at 84:3-6 ("[H]eat is [the] amount of energy. Heat *flux* [is the] amount of energy that [is] passing across a given area for a given period of time.") (emphasis added).

[33] *See* '397 Patent at col. 1:27-43; *id*. at col. 2:38-57.

measurements. . . ."[34] The sixth variable, *i.e.*, the output of the '397 algorithm, or T_{avg}, is identified by the '668 Patent as local body temperature.[35]

The '668 Patent further states that T_{avg} is calculated "using a function including the time-dependent parameters [of temperature change][;]"[36] another unsurprising statement, given that the inputs to the '397 algorithm (time-dependent temperature measurements taken by two sensors) correspond to the time-dependent parameters of temperature change used in the empirical formula disclosed in the Appendix.[37] (In my *Markman* order, I held that "'time-dependent parameters of temperature change' encompasses straight temperature difference [*e.g.* the reading of sensor one at interval ten minus the reading of sensor one at interval two] as

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[34] '668 Patent at col. 2:8-12 ("The thermometer is configured to perform the heat flux calculation so as to derive a value of the local temperature. The local temperature, together with the temperature measurements and the time dependent parameters of temperature change may then be used to calculate a core body temperature. The calculation is typically based on an empirically derived formula based on the aforementioned parameters.")

[35] *See id*. *See also id*. at col. 7:12-17 ("The formula [disclosed in the Appendix] is based on fitting a linear equation comprising several temperature-related parameters to clinically measured values of core body temperature. The temperature related parameters include sensor temperature readings, time-dependent temperature rates of change, and the value of local body temperature determined by the '397 algorithm.").

[36] *Id*. at col. 2:42-44.

[37] *See* '397 Patent at col. 4:64-67.

well as rates of temperature change.")[38]

ii. Prosecution History

During the prosecution history of the '668 Patent, the Examiner issued a final rejection holding Claims 1-13, 15, 19, 22-28, 33, and 36-38 as obvious over two references, "Fraden," which discloses calculating a deep tissue temperature at the forehead, and "Takashi," which discloses that the deep tissue temperature underestimates core temperature.[39] Yarden overcame this prior art by claiming that Fraden calculated deep tissue temperature, but taught away from correcting to core temperature by assuming that deep tissue temperature was a reliable approximation of core temperature.[40] Thus, the prosecution history record estops Medisim from denying that deep tissue temperature may be calculated by applying an infrared

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[38] *Markman* Op., 2011 WL 2693896, at *8.

[39] *See* '668 File History, 4/2/09 Final Rejection ¶ 2. Fraden, US Patent Application Publication 2005/0043631, discloses a thermometer that utilizes infrared technology. According to Yarden, Fraden "calculates deep tissue body temperature from time dependent parameters, but does disclose the additional step of correcting the deep body temperature to a core body temperature." *Id*. Takashi, an article from the Japanese Journal of Anaesthesiology, discloses a study showing that non-invasive forehead deep tissue thermometry, such as Fraden, underestimates the actual value of the core body temperature. *See id*.

[40] *See* '668 File History, 9/6/09 Response to Office Action at 10 ("Applicant respectfully disagrees and respectfully submits that it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Fraden's temperature probe to adjust or correct the deep tissue temperature calculated by the probe.").

thermometer to a patient's forehead.[41]

The Examiner also considered U.S. Application No. 60/572,651 (the "'651 Provisional"), a provisional patent application filed by Yarden prior to his application for the '668 Patent. The '651 Provisional is entitled "System for fast, non-invasive and accurate measurement of an object's temperature."[42] A fuller account of it is provided below.

2. Procedural History

After my *Markman* ruling, the parties made cross-motions under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[43] as well as Rules 702 and 403 of the Federal Rules of Evidence, to exclude the testimony of various experts. I ruled on these motions in an Opinion and Order dated March 6, 2012 (the "*Daubert*

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[41] *See Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1266 (Fed. Cir. 2012) ("A patentee's statements during reexamination can be considered during claim construction, in keeping with the doctrine of prosecution disclaimer."). The jury heard testimony supporting the same proposition. *See* Tr. (Direct Examination of David Lipson ("Lipson Direct") at 776:16-23 (discussing infrared technology) ("Q. If you take such a measurement at the temple, what temperature will you be calculating directly? A. If you are reading at this area which is right above, say, the temporal artery, you are reading what is now commonly referred to as the local deep tissue. It is the temperature under the skin in the tissue between, essentially, the artery and underneath the skin.").

[42] *See* '668 Patent at 2 (listing the '651 Provisional among the references considered by the Examiner).

[43] 509 U.S. 579 (1993).

Opinion" or "*Daubert* Op."), and on the motion for reconsideration subsequently brought by Medisim in an order dated April 23, 2012 (the "*Daubert* Reconsideration Op."). The parties then brought cross-motions for summary judgment. I decided these motions in an Opinion and Order dated November 28, 2012 (the "Summary Judgment Opinion" or "S.J. Op."). The relevant portions of these pre-trial rulings are summarized below.

a. The *Daubert* Opinion

The Summary Judgment Opinion provides the following summary of my rulings on the parties' *Daubert* motions:

> 1) Jack Goldberg—BestMed's expert on the validity of the '668 Patent—is qualified to opine in the area of digital, conductive thermometry. Goldberg may offer the following opinions: (1) that the specification of the '668 Patent does not enable the full scope of the claimed invention; (2) that Medisim's FHT-1 Digital Temple Thermometer . . . calculates core body temperature and therefore anticipated the '668 Patent; (3) that the FHT-1 calculates deep tissue temperature; and (4) that BestMed has not infringed Medisim's intellectual property. . . .
>
> 2) Dr. David Lipson—Medisim's expert on the validity of the '668 Patent—may opine that BestMed's KD-2201 thermometer meets the core body temperature limitation of the '668 Patent. Lipson may also testify that the KD-2201 thermometer meets the deep tissue temperature limitation of the '668 Patent, but only to the extent that he bases his opinion on the 510(k) letters and deposition testimony of K-Jump witnesses referenced in his

report.[44]

Lipson sought to testify that the accused device, BestMed's KD-2201 thermometer, met the deep tissue temperature limitation of the '668 Patent. In support of this conclusion, Lipson offered: (1) his own testing, which supposedly indicated that the KD-2201, a single-sensor conduction thermometer, measures deep tissue temperature when placed in 'test mode' (*i.e.*, a factory calibration mode where the actual temperature reading of the sensor is obtained, as opposed to a derived temperature), applied to the external skin, and allowed to reach thermoequilibrium; (2) the submissions that K-Jump, the manufacturer of the accused device, made to the FDA (the "510(k) Letters") describing the accused device; and (3) evidence drawn from the deposition of employees at K-Jump who were involved with designing the accused device (the "K-Jump Depositions").[45]

In the *Daubert* opinion, I found that the competent evidence of record showed that calculating a deep tissue temperature by measuring the thermoequilibrium temperature at the skin's surface was possible only through the zero-heat flux method, which requires at least two sensors and a heating element. I

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[44] S.J. Op., 2012 WL 5954757, at *3 (citing *Daubert* Reconsideration Op., No. 10 Civ. 2463, 2012 WL 1450420, at *2 (S.D.N.Y. Apr. 23, 2012); *Daubert* Op., 861 F. Supp. 2d 158, 167-74 (S.D.N.Y. 2012)).

[45] *See Daubert* Reconsideration Op., 2012 WL 1450420, at *2.

also found that utilizing the zero-heat flux method is an impossibility with the accused device, which lacks a heating element and has only one sensor.[46] On the basis of this finding, I entirely excluded, as an *ipse dixit*, Lipson's conclusion that the accused product meets the deep tissue temperature limitation of the '668 Patent.[47]

On reconsideration, despite having grave doubts about Lipson's ultimate conclusion that the accused product meets the deep tissue temperature limitation,[48] I amended my *Daubert* ruling to allow Lipson to testify to this conclusion, but only on the basis of the K-Jump Depositions and the 510(k)

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[46] *See Daubert* Op., 861 F. Supp. 2d at 175 & 175 n.121 (citing Michiaki Yamakage & Akiyoshi Namiki, *Deep Temperature Monitoring Using a Zero-Heat-Flow Method*, 17 J. Anesthesia 108, 111 (2003); Daniel I. Sessler, *Temperature Monitoring and Perioperative Thermoregulation*, 109 Anesthesiology 318, 319 (2008). Prior to trial, the parties stipulated that "[t]he scientific literature of record in this case shows that deep tissue temperature can be calculated from the skin's surface using zero-heat-flux." Stip. Facts ¶ 9.

[47] *See Daubert* Op., 861 F. Supp. 2d at 175-76 ("Lipson's determination that the KD-2201 measures deep tissue temperature at the skin surface is an unsupported *ipse dixit* conclusion. . . . Accordingly, Lipson may not testify that the KD-2201 meets the deep tissue temperature limitation of the '668 Patent.") (citations omitted).

[48] *See Daubert* Reconsideration Op., 2012 WL 1450420, at *2 (S.D.N.Y. 2012) ("I have serious doubts regarding whether Lipson's 'deep tissue temperature' opinions are correct.").

Letters.[49] Lipson remained barred from testifying on the basis of his "flawed empirical testing" of the accused device in test mode.[50] The rationale for my holding on reconsideration was that, although it was highly improbable that Lipson's testimony based on the K-Jump Depositions and the 510(k) Letters would ultimately be *sufficient* to prove that the accused product met the deep tissue temperature limitation, such testimony was nevertheless *admissible* under the standard established by *Daubert*.[51]

b. Medisim's Motion for Summary Judgment of No Inequitable Conduct

i. Decision

BestMed did not move for summary judgment on anticipation. However, Medisim raised a related issue by moving for summary judgment to dismiss BestMed's counterclaim for inequitable conduct. Inequitable conduct is a complete bar to enforcement of a patent, and may be proved by "clear and

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[49] *See id*.

[50] *Id*.

[51] *See id*. ("Because the Federal Rules of Evidence — and the case law in this Circuit — favor the admissibility of expert testimony and because courts should focus on an expert's methodology rather than his ultimate conclusions, . . . [I] conclude that Lipson may testify that the KD-2201 meets the 'deep tissue temperature' limitation of the '668 Patent. Accordingly, I now hold that he may give such testimony, insofar as it is based on the [K-Jump Depositions and the 510(k) Letters].").

convincing evidence [] show[ing] that the applicant made a *deliberate* decision to withhold a *known* material reference."[52]

One of the grounds alleged by BestMed in support of its counterclaim was that the FHT-1 anticipated the '668 Patent, and that Yarden therefore engaged in inequitable conduct when he failed to disclose Medisim's pre-critical date sales of the FHT line of thermometers to the PTO during the process of applying for the '668 Patent.[53] BestMed also argued that the '651 Provisional did not constitute prior art, because it was not published until after the critical date of the '668 Patent.[54]

In support of its motion for summary judgment on inequitable conduct, Medisim presented undisputed evidence that Yarden disclosed the '651 Provisional to the Examiner through an Information Disclosure Statement sent to the PTO on June 26, 2007, and that the Examiner checked a box indicating that he had reviewed it as prior art.[55] Medisim also asserted that during the prosecution of the '668 Patent, Yarden had a good faith belief that the '651 Provisional (which

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[52] *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (quotation marks and citations omitted) (emphasis in original).

[53] *See* S.J. Op., 2012 WL 5954757, at *18 (citations omitted).

[54] *See id*.

[55] *See id*. at *19 (citation omitted).

does not explicitly mention the FHT line of thermometers, or Medisim's commercial activities): (1) embodied the same technology as the FHT-1; and (2) did not meet the deep-tissue temperature limitation of the '668 Patent, and therefore was not anticipatory.[56] Based on these assertions, Medisim argued that Yarden had discharged his duty of disclosure to the PTO.[57]

On the strength of this argument, I granted summary judgment dismissing BestMed's inequitable conduct counterclaim. My reasoning was that, regardless of the merits of BestMed's underlying anticipation argument, there was insufficient evidence of Yarden's culpable state of mind to permit the issue to go to a jury.[58] As a consequence of prevailing on summary judgment, Medisim is judicially estopped from denying that: (1) the '651 Provisional is prior art, and therefore intrinsic evidence;[59] (2) the '651 Provisional describes the technology of the FHT-1 thermometer; and (3) Yarden applied for the '668 Patent on the basis of his belief that the FHT-1 did not meet the deep tissue limitation of the '668

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[56] *See id*. at *18-19.

[57] *See id*.

[58] *See id*.

[59] *See Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1372 (Fed. Cir. 2002) ("Prior art cited in the prosecution history falls within the category of intrinsic evidence.").

Patent.[60]

ii. The Anticipation Evidence Advanced by BestMed

In its unsuccessful opposition to Medisim's motion for summary judgment on inequitable conduct, BestMed offered the following evidence of anticipation (a ground upon which it did not bring a dispositive motion prior to trial): (1) Goldberg's opinions; (2) Yarden's deposition; (3) Medisim's marketing descriptions of its technology; and (4) the description of the invention in the '651 Provisional.[61] The former three pieces of evidence ultimately reached the jury in pertinent part. As for the '651 Provisional, although it was part of the intrinsic

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[60] *See, e.g., Intellivision v. Microsoft Corp.*, 484 Fed. App'x 616, 619 (2d Cir. 2012) (non-precedential) ("'[J]udicial estoppel[] generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase.'") (quoting *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (further quotation marks and citations omitted). This application of judicial estoppel is in accord with the testimony heard by the jury. *See* Tr. (Yarden Direct) at 106:9-15 ("We call it at that time FHT which is forehead thermometer, that was the previous model that we had, and . . . just to answer some issue that was raised yesterday saying that we didn't disclose the fact that we had this forehead thermometer in front of the [E]xaminer. Well, yes, we did, because if you look into this document which is now right on the ['668] [P]atent [*i.e.*, the '668 Patent's list of references, which mentions the '651 Provisional], we did disclose it indeed to the examiner."); *id*. (Medisim Summation) at 1647:4-10 ("It was clear, as Mr. Yarden testified, that the FHT-1 product was before the examiner who examined the '668 [P]atent, it was referenced in a provisional patent application, he testified about that. Another non-issue, another smokescreen set up to divert your attention.").

[61] *See* S.J. Op., 2012 WL 5954757, at *19.

evidence, it was not presented to the jury in *toto*; rather, it was presented to the jury by way of the parties' experts' reports.

Nevertheless, it is instructive — although unnecessary to resolving this motion — to consider the teachings of the '651 Provisional with respect to the deep tissue temperature limitation.[62] The '651 Provisional discloses a multi-sensor thermometer that measures time-dependent parameters of temperature change, and utilizes the '397 algorithm in order to calculate "inner body temperature[,]" which it refers to as "T_{deep}," from temperature measurements made at the skin's surface.[63] It also explicitly provides for correcting this "inner body temperature" to core temperature, stating that: "[t]he invention under discussion also makes use of the

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[62] I take judicial notice of the public record of the '651 Provisional under Fed. R. Evid. 201(b)(2). Notice is justified because the '651 Provisional is a public record filed with the PTO, and, moreover, one that the parties placed into the record, with a full and fair opportunity to be heard on it, during the summary judgment stage of the case. *See Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 2010-1500, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010) (non-precedential) (taking judicial notice of patent applications). *Cf. Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 n.3 (Fed. Cir. 1990) (taking judicial notice of first office action); *Iconfind, Inc. v. Google, Inc.*, No. 11 Civ. 319, 2012 WL 158366, at *1 (E.D. Cal. Jan. 18, 2012) (taking judicial notice of patent's prosecution history).

[63] 5/20/04 '651 Provisional Specification, ¶ 1.9 ("Measuring of inner body temperature (hereafter T_{deep}) can be done on the exterior surface of the body."). *Cf.* 5/20/04 '651 Provisional Introduction at 5 ("The basic principal [sic] is to measure temperature and heat fl[u]x on the surface and based on that estimat[e] the value of deep tissue temperature.")

value of T_{deep} and the measured values of [the temperature on the skin's surface] and [heat flux measured on the skin's surface] as [an] input for empirically correcting the model by the additional term [change in heat flux] *in order to extract the core body temperature* from the local parameters."[64] Finally, it distinguishes between skin surface temperature and T_{deep} by stating that temperature measured at the skin's surface varies more with environment conditions than T_{deep}.[65]

In short, the '651 Provisional strongly suggests that the FHT-1 thermometer anticipates the '668 Patent. Indeed, on summary judgment, the only argument that Medisim could muster against the obvious inference that deep tissue temperature and T_{deep} are one and the same is that the '651 Provisional does not use the same *terms* as the '668 Patent, even though it describes the same process.[66] Had BestMed moved for summary judgment on anticipation, rather than defending

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[64] 5/20/04 '651 Provisional Summary of the Invention at 4.

[65] *Compare id.* ("However, the value of $T_{surface}$ [temperature at the skin's surface] is different from the value of T_{deep}. [Because] . . . the skin [is] exposed to the environment, $T_{surface}$ [] represent[s] also that effect and not only the value of T_{deep}.") *with* '668 Patent at col. 7:1-4 ("The local temperature determined by the '397 algorithm is less affected than the surface temperature at the measurement site is to external factors such as ambient temperature and humidity.").

[66] *See* Reply in Support of Medisim's Motion for Summary Judgment of No Inequitable Conduct ("Medisim IC Reply"), Doc. No. 116, at 5 n.2 ("The '651 Provisional . . . does not mention 'deep tissue' temperature as claimed in the '668 Patent, but rather refers only to 'T_{deep},' which expressly is defined in the '651 Provisional as an 'inner body temperature.'").

Medisim's motion for no inequitable conduct, it is likely that the motion would have been granted.[67]

The suspicion that BestMed could have ended this action earlier by seeking summary judgment on anticipation is strengthened by Yarden's deposition testimony. In a portion of his deposition that was subsequently displayed to the jury, Yarden testified that the FHT-1 "receives a value based on [an] algorithm that it is implementing the heat flow calculation [*i.e.*, the '397 algorithm] . . . it takes this temperature that was coming out of the algorithm of the heat flow and puts it into a third order polynomial which produces the [core] body temperature [*i.e.*, corrects to core]."[68]

The similarity between Yarden's description of the FHT-1 and the invention claimed by the '668 Patent is unmistakable. Moreover, in denying this similarity on summary judgment, Medisim offered only the conclusory testimony

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[67] *Cf.* S.J. Op., 2012 WL 5954757, at *19 ("Goldberg's opinion [on anticipation] may be relevant to whether Yarden was wrong, but it is irrelevant to whether Yarden believed the devices were covered by the '668 Patent and intentionally withheld information regarding their sales so as to deceive the PTO.") (citation omitted).

[68] *Id.* at *21 n.223 (quoting 2/2/11 Deposition of Moshe Yarden at 162:6-22). *Cf.* Tr. (Redirect Examination of Goldberg ("Goldberg Redirect")) at 1398:13-1399:18 (discussing the portion of Yarden's deposition just quoted and pointing out the similarity between Yarden's description of the FHT-1 and the '668 Patent).

of Yarden that the FHT-1 does not calculate deep tissue temperature, and the misleading and irrelevant argument that, at one point, the '668 Patent states that the '397 algorithm is only an exemplar of how deep tissue temperature may be calculated.[69] In sum, BestMed probably erred by failing to move for summary judgment on anticipation.

3. Trial Evidence

This section summarizes the relevant trial evidence not discussed above. *First*, it presents the testimony of Yarden and Lipson. *Second*, it presents the testimony of Goldberg, and *third*, it presents evidence relating to Medisim's pre-litigation descriptions of its technology, as well as evidence relating to the shift between the FHT-1 and the FHT-1A, which Medisim contends was the first thermometer to embody the '668 Patent.

a. Yarden's Testimony

i. The Innovation of the '668 Patent

At trial, Yarden testified that, prior to inventing the '668 Patent, he

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[69] *See* Medisim IC Reply at 4-5 (citing '668 Patent at col. 1:65-2:5). The argument is misleading because, as discussed above, the '668 Patent states at multiple points that deep tissue temperature is derived from the '397 algorithm, when that algorithm is implemented by devices like the FHT-1. It is irrelevant because meeting the deep tissue temperature limitation only requires that the FHT-1 "calculate . . . a deep tissue temperature," not that it exhaust the possible methods for calculating a deep tissue temperature.

had determined that Medisim's FHT-1 and FHT-2 thermometers required improvement, because they were inaccurate in extreme ambient temperatures (*e.g.*, a very hot room).[70] Yarden further testified that, some time after filing the '651 Provisional,[71] his research revealed that a temperature sensing patch attached to the surface of a patient's forehead would settle on a temperature that was much lower than either core temperature or oral temperature after approximately ten minutes.[72] He referred to this temperature as deep tissue temperature.[73]

Yarden further testified that the contemporaneous state of the art inaccurately treated deep tissue temperature as a reliable approximation of oral or core temperature, despite the fact that deep tissue temperature was "not . . . core or even close to it."[74] He then testified that his discovery that a user's deep tissue

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[70] *See* Tr. (Yarden Direct) at 101:16-24.

[71] *See id*. (Yarden Cross) at 264:10-14 ("Q. This aha moment occurred after you had filed the provisional specification that you thought about yesterday, is that right? A. That's right. If I recall, the provisional was way back 2002 or 2003, so that's right.").

[72] *See id*. (Yarden Direct) at 102:1-103:21.

[73] *Id*. at 103:22-104:3 ("[The temperature display of a temperature sensing patch applied to a patient's forehead for ten minutes] would be the local temperature, namely [] the temperature that will be prevailing under the skin, however this will not be the core or even close to it.").

[74] *Id*. at 104:3. *See id*. at 103:3-5 ("[T]he expectation was that [by leaving the temperature patches on patient's foreheads for ten minutes] we [would] get something which is very close to the patient temperature like the oral

temperature could be obtained by allowing a temperature sensing patch placed on the user's forehead to reach thermoequilibrium led him to improve upon the FHT line of thermometers with the '668 Patent, which first calculates a deep tissue temperature, and then corrects to core.[75]

ii. The Deep Tissue Temperature Limitation

Yarden testified that the portion of the formula disclosed in the Appendix incorporating T_{avg} calculates deep-tissue temperature, and that the balance of the formula corrects to core temperature.[76] Per Yarden's testimony, then, the embodiment of the '668 Patent disclosed in the Appendix calculates deep tissue temperature by solving the following equation: deep tissue = $(C_3 \times T_{avg}) + (C_4 \times T_{avg}^2) + (C_7 \times T_{avg}^3) + C_6$, where terms of the form C_X are constants.[77] This derived deep tissue temperature is then corrected to core temperature by the

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temperature.").

[75] *See id*. at 103:16-21 ("So, combining [my review of the prior art] with the patch results that we had, I came to the conclusion that having a thermometer that we'll be able to do a dual step[,] namely first calculate the local temperature and then correct it to the core temperature, it will be more accurate and will probably address our need for improvement of our previous models."). Notably, all of the features that Yarden described as essential to his innovation are present in the '651 Provisional.

[76] *See id*. at 110:1-12.

[77] *See* '668 Patent at col. 9:62-63.

balance of the equation disclosed in the Appendix. On the basis of this characterization of the Appendix, Yarden further testified that T_{avg} is not, itself, deep tissue temperature; for if it were, there would be no reason to perform the operations listed above in order to arrive at deep tissue temperature.[78]

iii. The FHT-1 Thermometer

On direct examination, Yarden testified that the FHT-1 employs "a fixed baseline . . . representing the lower end of the temperatures of the core body temperatures[,]" and that it "use[s] the output of the heat flux method [] to calculate the difference between that baseline and the" approximation of core temperature that the FHT-1 ultimately displays to the user.[79] Yarden likened this "fixed baseline" to a "reference line which represent[s] the lower end of the measurement range [of core temperature]. . . ."[80] Yarden testified that the "fixed baseline" employed by the FHT-1 could not be the same as a user's deep tissue temperature, because it has a constant value.[81]

On cross-examination, Yarden testified that the FHT-1 uses the heat-

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78 *See* Tr. (Yarden Direct) at 110:13-22.

79 *Id*. at 115:21-116:1.

80 *Id*. at 89:17-18.

81 *See id*. at 116:8-23.

flux algorithm disclosed in the '397 Patent in order to arrive at an intermediate temperature, and then performs the "further step" of "calculating [the] difference . . . above a base line" in order to arrive at the user's "core body temperature."[82] Yarden also testified on cross-examination that the '397 Patent discloses a general procedure by which the heat-flux method may be used in order to derive body temperature, but that additional steps were needed to "in order to derive [] local deep tissue [temperature]. . . ."[83] Soon after, Yarden acknowledged that the FHT-1 takes sensor readings, processes them using the '397 algorithm to arrive at an intermediate value, and then applies an algorithmic process in order to display an approximation of core temperature, but inexplicably insisted that this was not a "two step" process.[84] Yarden then testified that the limitations of the heat-flux

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[82] *Id*. (Yarden Cross) at 270:9-10; 271:4-7 ("The further step is taking that T_{avg} that we're getting out of the '397, and then calculating difference, which is around for a normal person around 2 to 3 degrees centigrade above a base line as we just show in the slide the other day.").

[83] *Id*. at 267:17-21.

[84] *See id*. at 273:11-274:1 ("Q. All right. So there is a second step after you obtain the initial value using the heat transfer algorithm of the '397 patent, correct? A. That's correct. Q. So will you agree with me that the FHT-1 device also uses a two step process to obtain the final result? A. Again, just to clarify. Q. No, yes or no, please? A. No. . . . In the sense that you mention. Q. Excuse me? A. Correction, two step, then the answer is no. Q. All right. But you do something to the value that you obtain or you change the number in some manner that you obtained after the FHT-1 has done the heat transfer algorithm calculation, correct? A. That's correct.").

algorithm disclosed in the '397 Patent are "explain[ed] clearly in the '668 [Patent's] appendix."[85]

On re-direct, Yarden identified the value of the fixed baseline as 95.7° Celsius.[86] Regarding this testimony, Medisim asserts that "Yarden misspoke and clearly meant Fahrenheit rather than Celsius."[87] Finally, Yarden testified that the invention embodied in the '397 Patent does not "measure deep tissue temperature."[88]

b. Lipson's Testimony

i. Deep Tissue Temperature

Like Yarden, Lipson testified that one of the advances of the '668 Patent is that it differentiated between core temperature and deep tissue temperature, whereas the prior art had equated the two.[89] Lipson further testified that this supposed false equivalence between core and deep tissue temperature

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[85] *Id*. at 267:21-22.

[86] *Id*. (Redirect Examination of Moshe Yarden ("Yarden Redirect")) at 324:3-6.

[87] Opp. Mem. at 4 n.6. Water boils at a temperature of 100°C under normal atmospheric conditions. A body temperature of 95.7°C would cause instant death.

[88] Tr. (Yarden Redirect) at 324:18-20.

[89] *See id*. (Yarden Direct) at 102:5-104:3; *id*. (Rebuttal Redirect Examination of Dr. David Lipson ("Lipson Rebuttal Redirect")) at 1554:2-6.

provides a non-invalidating explanation for certain of Medisim's pre-'668 Patent descriptions of its technology.[90]

On cross-examination, Lipson testified that 95°F is a "pretty reasonable estimate for a healthy person's [deep tissue temperature]. . . ."[91] He then testified that deep tissue temperature is lower than core temperature and higher than surface temperature, and, when measured at a healthy person's temple, will typically fall between 94°F and 98°F.[92]

ii. The FHT-1 Thermometer

Lipson testified that the FHT-1 "calculates some intermediate temperature and then displays an estimate of core body temperature[,]"[93] but does not calculate local deep tissue temperature.[94] Lipson further testified that he based this conclusion on his conversations with Yarden about the FHT-1's design, his

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[90] *See id*. at 1554:13-17. Lipson was not entirely consistent on this point: when asked whether a pre-litigation document of Medisim's referring to "deep tissues' temperature" could be referring to "pulmonary artery temperature," he replied "no way." *Id*. (Rebuttal Cross-Examination of Dr. David Lipson ("Lipson Rebuttal Cross")) at 1543:6-8.

[91] *Id*. (Cross-Examination of Dr. David Lipson ("Lipson Cross")) at 867:18-19.

[92] *See id*. at 869:18-870:7.

[93] Tr. (Lipson Rebuttal Redirect) at 1552:23-25.

[94] *Id*. at 1553:1-2.

own tests (in which he used the FHT-1 on himself), and "marketing information that suggested that[,]" with the FHT-1, Medisim was "directly trying to calculate core temperature at the temple site but not doing it in a manner described in the '668 patent."[95]

In his rebuttal testimony, Lipson describes his testing of the FHT-1 as follows:

> When I just tested [the FHT-1] on myself the software listing shows a particular equation that is the final one used for the prediction of temperature and I had the ability to ask Mr. Yarden about what that was. So, I simply did a couple of measurements on myself with the FHT-1 temperature and the key number that comes out of that equation was giving me a body temperature — or giving me a temperature number of around 92 degrees. But, in test mode, factory examination mode, it correctly read my forehead as being 95 degrees, my temple area. So, I knew that was just some intermediary result of the algorithm and the display temperature was giving me a reasonable reading from my body temperature. So, I was able to say between the test, the algorithm and making sure that I understood what the algorithm was by talking to Mr. Yarden, the FHT-1 does not calculate a local deep tissue and then correct it to core.[96]

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[95] *Id*. (Rebuttal Testimony of Dr. David Lipson) ("Lipson Rebuttal")) at 1522:15-18.

[96] *Id*. at 1521:14-1522:4. Lipson went on to testify that he had the FHT-1 for a "short period of time," and only tested it on himself. *See id*. at 1522:10-11. The jury heard abundant testimony that, when it is placed into 'test mode,' the FHT-1 thermometer displays the *actual* temperature reading of the sensors, as opposed to a derived value. *See, e.g., id*. (Yarden Cross) at 289:1-21 (testifying as to the procedure for placing the FHT line of thermometers into 'test mode,' and differentiating between "technical, lab accuracy, which will show you the actual

Shortly thereafter, and also during his rebuttal, Lipson testified, also on the basis of testing the FHT-1 thermometer on himself, that:

> There is an equation that actually is used at the final step of the operation of the [FHT-1] thermometer and that equation tells you how the display temperature is going to be calculated based on what is referred to as T-average[,] which is an intermediate result the thermometer calculates from making measurements from the temperature sensors. That equation was confirmed by Mr. Yarden, but when you actually put in an indicated temperature which you can measure and look at the local deep tissue temperature, you find out it can't make any sense.[97]

On cross-examination, Lipson testified that the sole distinction between the FHT-1 and the '668 is that the former does not calculate deep tissue temperature, and conceded that, if the FHT-1 calculated deep tissue temperature, it would anticipate the '668 Patent.[98] Moments earlier, in the context of obviousness,

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temperature sensed by the sensor[,]" and "clinical accuracy[,] where you would like to see how accurate . . . the device [will be] . . . [when] used in its normal mode").

[97] *Id*. (Lipson Rebuttal) at 1524:6-15. Yarden also repeatedly testified that the intermediate temperature of the FHT-1 is the output of the '397 algorithm, and that the value derived from the '397 algorithm is then used in an algorithm that estimates core temperature. *See* Tr. (Yarden Redirect) at 324:5-9; *id*. (Yarden Cross) at 271:4-7; *id*. at 272:8-10. Lipson made no mention of the "fixed baseline" referenced by Yarden.

[98] *See id*. (Lipson Rebuttal Cross) at 1539:17-22 ("Q. So the difference — we're talking about deep tissue temperature. If the intermediate temperature calculated by the FHT-1 thermometer, this the prior art FHT-1 thermometer, is a deep tissue temperature, then does it anticipate the claims of the '668 patent? A. It would certainly anticipate claim one.").

Lipson had engaged in the following colloquy with the Court:

> THE WITNESS: [O]nce I understand [] what the temperature I'm looking at is, and I know I'm in an environment where it's cooling, I just put a little insulation around the transducer, the thermistor, and I can [take] [an] external surface measurement, and I know it's going to look at the tissue underneath the skin.
>
> THE COURT: So you're saying you can take an invasive thermometer and put it on your temple, put some insulation on, and thereby replicate this process of getting . . . the deep tissue [temperature]?
>
> THE WITNESS: *That's essentially what the FHT-1 did*. Yes, I could do that.[99]

c. Goldberg's Testimony

Goldberg testified at trial that the FHT-1 met all the claim limitations of the '668 Patent.[100] Regarding the deep tissue temperature limitation, Goldberg testified — while a portion of the FHT-1's source code was on display — that:

> The routine [*i.e.*, the portion of the source code allegedly responsible for calculating deep tissue temperature] takes these temperature change parameters and processes them in a manner consistent with arriving at a deep tissue temperature. It is important to note that we know from other documents that the FHT-1 is utilizing methodology that's described in the '397 patent, that it uses two sensors, that it uses the heat flux algorithm, and because of that the calculation that's here is consistent with

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[99] *Id*. at 1536:5-17 (emphasis added).

[100] *See id*. (Direct Examination of Jack Goldberg ("Goldberg Direct")) at 1189:11-14.

the calculation of a deep tissue temperature.[101]

In short, Goldberg identified for the jury a portion of the source-code of the FHT-1 that is consistent with the '668's teachings for arriving at a deep tissue temperature, *i.e.*, practicing the '397 algorithm.[102] Medisim's cross-examination of Goldberg on the deep tissue limitation was confined to attempting to show that Goldberg was merely parroting the report of Gilliland, BestMed's consulting expert. That line of questioning did not bear fruit.[103]

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[101] *Id*. at 1188:13-20 (citing Defendant's Trial Exhibit ("DX")-ON, source-code from the FHT-1, at MED016839).

[102] *See id*. at 1188:13-20. *See also id*. at 1197:15-24 (Goldberg testimony that the FHT-1 "estimat[es] the deep tissue temperature by solving a time-dependent heat conduction transfer equation" on the basis that "it utilizes the heat conduction methodology of R.A.T.E. [Medisim's trademarked description of its technology], and . . . the software shows the step."); *id*. at 1199:12-14 ("I can see the function that calculates the deep tissue temperature and utilizes the said time-dependent parameters right there in the software."). Goldberg also identified a portion of the FHT-1's source code that implements a third-order polynomial, of the sort found in the Appendix, and, on this basis, testified that the FHT-1 practiced the correcting to core limitation of the '668 Patent. *See id*. at 1198:10-15 ("Again, you know, the software [of the FHT-1] shows this polynomial function. The sub-routine is actually named P-o-l-i-n-o-m, Polinom, and we know that it calculates a deep tissue temperature, and we know that it corrects to core. So this limitation is also practiced through the use of the device.").

[103] *See id*. (Goldberg Cross) at 1317:3-1326:25. Medisim's unsuccessful attempt to depict Goldberg as a mere conduit for Gilliland echoed its unsuccessful motion to strike the portions of Goldberg's report analyzing the FHT-1 under *Daubert*. *See Daubert* Op., 861 F. Supp. 2d at 169 (concluding that Goldberg was entitled to reference Gilliland's report, because Goldberg conducted an independent investigation).

d. Medisim's Pre-Litigation Descriptions of Its Technology

Medisim gave its heat-conduction thermometer technology the commercial name R.A.T.E., which stands for "Rapid Accurate Temperature Establishment."[104] One of the bases for BestMed's anticipation argument is that, prior to this action, Medisim described its R.A.T.E. technology in terms strikingly similar to the operation of the '668 Patent.

For example, Yarden sent an e-mail to K-Jump and BestMed on May 9, 2003 for the purposes of explaining Medisim's technology.[105] This e-mail contains an attachment, titled Products Outline, that discloses that R.A.T.E. technology employs a heat-flux algorithm identical to that taught by the '397 Patent.[106] This attachment also states that "in R.A.T.E™ [technology] extrapolation is not performed. In other words, a future value is not predicted but a calculation made, in real time, of the temperature existing under the skin."[107] The

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[104] Tr. (Yarden Direct) at 86:1-4.

[105] *See* DX-TK, 5/9/03 e-mail from Yarden to BestMed and K-Jump Officials, at K-J 01780 ("Attached please find some info regarding our company and technology for tomorrow['s] video-con.").

[106] *Compare id*. at K-J 01798-01799 *with* '397 Patent at col. 2:50-57.

[107] DX-TK at K-J 01803. The deep tissue temperature limitation of the '668 Patent states: "to calculate, a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature

Products Outline also contains a diagram depicting a cross section of tissue layers, running from "blood vessels," to "deep tissues," to "subcutaneous fat," to the "skin surface," and a probe pressed against the skin surface.[108] On direct examination, Stanley Cohen, BestMed's CEO, testified that he received no indication from Medisim that the technology described in the Products Outline was not incorporated into the FHT-1 thermometer, which BestMed began selling on behalf of Medisim shortly thereafter.[109]

Similarly, Goldberg testified that, in addition to the Products Outline attached to the May 9 e-mail, one of the documents that he relied upon in forming his conclusion of anticipation was another Products Outline released by Medisim prior to the critical date of the '668 Patent.[110] This document states that "[b]y utilizing the conductive R.A.T.E™ technology, FHT™ thermometers measure deep tissues' temperature and thus the effect of the environmental conditions is

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sensors. . . ." '668 Patent at col. 10:13-15.

[108] DX-TK at K-J 01789.

[109] *See* Tr. (Direct Examination of Stanley Cohen ("Cohen Direct") at 659:25-660:5 ("Q. Did Medisim ever advise you that [the R.A.T.E.] technology [explained in DX-TK] was not going to be used in the FHT-1 thermometer? A. No. Q. Did they ever advise you that this technology was not found in their FHT-1 thermometer? A. No.").

[110] *See id*. (Goldberg Direct) at 1188:21-1189:12.

minimized."[111] Yarden conceded that this document referred to the FHT-1,[112] but testified that its reference to "deep tissue*s'* temperature," as opposed to "deep tissue temperature," was merely meant to differentiate R.A.T.E. technology from infrared technology.[113]

e. The Shift from the FHT-1 to the FHT-1A

Yarden testified that the first Medisim product to incorporate the technology of the '668 Patent was the FHT-1A thermometer, which was first sold in mid-2007.[114] Yarden also testified that "there were phone calls, discussions, and there . . . was an e-mail where" BestMed and Medisim contemporaneously discussed the new technology allegedly embodied in the FHT-1A.[115]

On cross-examination, Yarden conceded that he had not personally informed BestMed of the switch from the FHT-1 to the FHT-1A, but believed that someone at Medisim had.[116] Yarden also testified that the FHT-1A looked the

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[111] DX-IF (Medisim Ltd. Products Outline, marketing literature prepared by Medisim some time between 2003 and 2006).

[112] *See* Tr. (Yarden Cross) at 303:15-20.

[113] *See id*. at 304:7-16.

[114] *See id*. (Yarden Direct) at 117:6-118:6.

[115] *Id*. at 176:11-14.

[116] *Compare id*. (Yarden Cross) at 303:11-15 (" Q. [W]hen the FHT-1 was replaced by the FHT-1A as you testified, yesterday you said that you did in

same as the FHT-1, but contained different internals, *i.e.*, it ran different source code and had a different circuit board.[117]

Beyond Yarden's testimony, no evidence of record supports the conclusion that the FHT-1A was significantly different from the FHT-1. No analysis comparing the FHT-1A's source code or internal architecture with the FHT-1 was presented to the jury. Nor did consumers appear to appreciate the difference between the products: the evidence of record shows that BestMed enjoyed the same sales with the FHT-1A as it had with the FHT-1.[118]

Furthermore, the uncontradicted evidence is that Medisim did not

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fact notify BestMed about that change. Do you recall that? A. Yes, but not me personally necessarily. I mean Medisim informed."), *with id*. (Yarden Direct) at 176:5-18 ("THE COURT: So, Mr. Yarden, if you would listen to this question: Prior to mid-2007, had you been in communication with the representatives of BestMed about your development of the technology behind the FHT-1A product? THE WITNESS: The answer is yes. . . . Q. Did you inform BestMed in advance before you started shipping them the FHT-1A thermometer rather than the FHT-1 thermometer? A. Yes.").

[117] *See id*. (Yarden Cross) at 294:7-14.

[118] *See id*. (Direct Examination of Robert McSorley, BestMed's expert on damages) at 1419:14-19 ("[A]fter this alleged transition from the FHT-1 to the FHT-1A, sales of BestMed [products] did not increase. There is a six quarter period which is a year and a half during which these alleged switch — the alleged FHT-1A was on the market where the sales were pretty much consistent from where they were in 2005, 2006 and 2007.").

suggest to BestMed that it mark the FHT-1A as "patent pending."[119] In fact, the only contemporaneous evidence of record showing that Medisim informed BestMed of the shift from the FHT-1 to the FHT-1A was an e-mail sent by a Medisim employee to Stanley Cohen, which references the FHT-1A in its subject line, but provides no indication that it embodies a new technology.[120]

C. Unjust Enrichment

1. The Parties' Contracts

Like many rivals, Medisim and BestMed were once allies. From November 2004 to May 2007, BestMed marketed and sold Medisim's digital, conductive forehead thermometers in the United States under the International Distributorship Agreement (the "IDA") entered into between the parties.[121] While the IDA was in effect, BestMed was privy to technical information concerning Medisim's thermometers, and received a draft of the thermometers' IFU.[122] By

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[119] *Id*. (Redirect Examination of Stanley Cohen) at 758:10-15.

[120] *See id*. (Cohen Direct) at 656:3-658:6 (discussing DX-PN — e-mail from Medisim employee to Cohen asking to switch the warehousing lot number of Medisim's thermometers — and testifying that he had no recollection of being informed that the FHT-1A embodied new technology).

[121] *See* 11/24/04 IDA, DX-TU.

[122] *See id*.

mid-2005, Medisim was supplying BestMed with its FHT-1 thermometer.[123]

As a result of a disagreement about the renewal of the IDA, the parties entered into a Purchase and Sale Agreement ("PSA"),[124] which commenced on May 1, 2008 and terminated on May 1, 2009.[125] Among other things, the PSA permitted the parties to sell competing products to customers as of May 1, 2008, so long as deliveries were not made prior to May 1, 2009.[126] Moreover, through the PSA, the parties waived any claims "arising from the actual or alleged performance, termination, breach or continuation of [the IDA] and the parties' subsequent correspondence relating to [the IDA] and the proposed renewal or replacement thereof."[127]

2. Procedural History

On summary judgment, BestMed moved to dismiss Medisim's unjust enrichment claim on the related grounds that: (1) it was just a catch-all for Medisim's other claims; and (2) that it was preempted. The motion was denied, on the basis that the Lanham Act does not preempt a state law claim of unjust

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123 *See* Tr. (Yarden Direct) at 90:15-19.

124 *See id*. at 198:1-201:20.

125 *See* PSA, DX-PM, at 00094.

126 *See id*.

127 *Id*. at 00095.

enrichment.[128]

3. Trial

Like the invalidity inquiry, the unjust enrichment inquiry was significantly narrowed prior to its submission to the jury. Medisim's claim for unjust enrichment was vaguely pleaded, and fell in the interstices of its claims for patent infringement, copyright infringement, unfair competition (state and federal), false advertising (state and federal), and Deceptive Acts and Practices.[129] Of these claims, federal unfair competition, false advertising, and Deceptive Acts and Practices were dismissed on summary judgment.[130] Moreover, Medisim's claim for copyright damages was dismissed prior to the case's submission to the jury.[131]

Ultimately the jury was charged with deciding whether "BestMed has been unjustly enriched by obtaining profits from the sale of its thermometers[,]" and in determining damages for unjust enrichment, was instructed to consider "the value of the profits that BestMed made from its sale of thermometers."[132] The jury

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[128] *See* S.J. Op., 2012 WL 5954757, at *14 ("[E]ven if Medisim's unjust enrichment claim duplicates its Lanham act claims . . . dismissal of [the] unjust enrichment claim is not warranted.").

[129] *See* Complaint, Doc. No. 1, ¶¶ 65-69.

[130] *See* S.J. Op., 2012 WL 5954757, at *1.

[131] *See* Tr. (JMOL Conference) at 1221:1-1223:1.

[132] *Id*. (Jury Instructions) at 1726:9:1727:2.

found against Medisim on its state unfair competition claim, which Medisim concedes "overlap[s] significantly" with its claim for unjust enrichment.[133]

III. LEGAL STANDARD

A. Judgment as a Matter of Law

In a case arising under the patent laws, the rules of the regional circuit governs the standard of review applicable to a JMOL motion.[134] In the Second Circuit, a Federal Rule of Civil Procedure ("Rule") 50(b) motion for JMOL may be granted only if "a reasonable jury would not have a legally sufficient evidentiary basis to find for the [non-movant] on that issue."[135]

"[A] district court can grant the motion only if after viewing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in favor of the non-moving party, it finds that there is

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[133] *Id*. (Charging Conference) at 1505:13-16 ("For its next motion Medisim asserts, as a matter of law, that it has prevailed on its New York unjust enrichment claim. The facts and circumstances overlap significantly with the unfair competition claim.").

[134] *See Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 18 (Fed. Cir. 2012).

[135] *Cameron v. City of New York*, 598 F.3d 50, 59 (2d Cir. 2010) (alteration in original) (quoting Fed. R. Civ. P. 50(a)(1)).

insufficient evidence to support the verdict."[136] Thus, JMOL is appropriate where "there exists such a complete absence of evidence supporting the verdict that the jury's findings could only have been the result of sheer surmise and conjecture, or the evidence in favor of the movant is so overwhelming that reasonable and fair minded [persons] could not arrive at a verdict against [it]."[137] "If the court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed."[138]

A motion under Rule 50(b) is properly made only if the movant "sought relief on similar grounds under Rule 50(a) before the case was submitted to the jury."[139] "'Generally a party is not entitled to [JMOL under Rule 50(b)] on any ground that [it] has not raised in a motion for a [JMOL under Rule 50(a)] . . .

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[136] *Fabri v. United Techs. Int'l, Inc.*, 387 F.3d 109, 119 (2d Cir. 2004) (citing *Tolbert v. Queens Coll.*, 242 F.3d 58, 70 (2d Cir. 2001)).

[137] *Tepperwien v. Entergy Nuclear Operations, Inc.*, 663 F.3d 556, 567 (2d Cir. 2011) (quotations marks and citations omitted, alterations in original).

[138] Rule 50(c)(1).

[139] *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486 n.5 (2008). *Accord Bracey v. Board of Educ. of City of Bridgeport*, 368 F.3d 108, 117 (2d Cir. 2004) ("A post-trial Rule 50(b) motion for judgment as a matter of law is properly made only if a Rule 50(a) motion for judgment as a matter of law has been made before submission of the case to the jury.") (collecting cases).

and the [Rule 50(a)] motion must have state[d] the specific grounds therefor.'"[140] In order to properly preserve a Rule 50(b) motion, "[t]he [pre-verdict] JMOL motion must at least identify the specific element that the defendant contends is insufficiently supported. . . . A generalized challenge is inadequate."[141]

B. New Trial

"Unlike a motion for judgment as a matter of law, a motion for a new trial may be granted even if there is substantial evidence to support the jury's verdict."[142] Nevertheless, "'[a] motion for a new trial ordinarily should not be granted unless the trial court is convinced that the jury has reached a seriously erroneous result or that the verdict is a miscarriage of justice.'"[143] A court may set aside the verdict and order a new trial even if no motion for JMOL was made under

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[140] *Northrop v. Hoffman of Simsbury, Inc.*, 12 Fed. App'x 44, 49 (2d Cir. 2001) (quoting *Smith v. Lightning Bolt Prods., Inc.*, 861 F.2d 363, 367 (2d Cir. 1988) (further citations omitted)).

[141] *Gierlinger v. Gleason*, 160 F.3d 858, 869 (2d Cir. 1998) (quotation marks and citations omitted).

[142] *Caruolo v. John Crane, Inc.*, 226 F.3d 46, 54 (2d Cir. 2000) (quotation marks and citation omitted).

[143] *Townsend v. Benjamin Enters., Inc.*, 679 F.3d 41, 51 (2d Cir. 2012) (quoting *Medforms, Inc. v. Healthcare Mgmt. Solutions, Inc.*, 290 F.3d 98, 106 (2d Cir. 2002)).

Rule 50(a).[144]

C. Patent Invalidity

1. Burden of Proof

Section 282(a) of Title 35 of the United States Code states that:

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.[145]

Invalidity defenses to patent infringement require proof by clear and convincing evidence.[146] Under the *Barbed-Wire*[147] doctrine,

> [C]orroboration is required of any witness whose testimony alone is asserted to invalidate a patent. Both physical evidence and oral testimony of a disinterested party can serve to satisfy the corroboration requirement. The sufficiency of the corroborating evidence is assessed according to the following factors: (1) the relationship between the

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[144] *See Bracey*, 368 F.3d at 117 (granting Rule 59 motion in the absence of Rule 50(a) motion). *Cf. Macquesten Gen. Contracting, Inc. v. HCE, Inc.*, 128 Fed. App'x 782, 784 (2d Cir. 2005) ("While MacQuesten failed during the trial to make a motion for judgment as a matter law pursuant to Rule 50(a), that is no impediment to a Rule 59(a) motion.").

[145] 35 U.S.C. § 282(a).

[146] *See Microsoft Corp. v. i4i Ltd. P'ship*, — U.S. — , 131 S.Ct. 2238, 2242 (2011).

[147] *The Barbed Wire Patent*, 143 U.S. 275, 284 (1892).

> corroborating witness and the alleged prior user, (2) the time period between the event and trial, (3) the interest of the corroborating witness in the subject matter in suit, (4) contradiction or impeachment of the witness' testimony, (5) the extent and details of the corroborating testimony, (6) the witness' familiarity with the subject matter of the patented invention and the prior use, (7) probability that a prior use could occur considering the state of the art at the time, (8) impact of the invention on the industry, and [(9)] the commercial value of its practice.[148]

2. Anticipation

Novelty is a requirement of patentability. A patent may not validly issue if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention[,]" or if the claimed invention was described in an earlier-filed patent or application by a different inventor.[149]

A patent claim that is not novel is said to be anticipated. "[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference."[150] "Anticipation is a question of fact reviewed for

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[148] *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1159-60 (Fed. Cir. 2004) (quotation marks and citations omitted) (alterations in original).

[149] 35 U.S.C. § 102(a).

[150] *Celeritas Techs., Ltd. v. Rockwell Intern. Corp.*, 150 F.3d 1354, 1361 (Fed Cir. 1998) (citing *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984)).

substantial evidence when tried to a jury."[151]

> Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses [sic] interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference. The testimony is insufficient if it is merely conclusory. And if the testimony relates to prior invention and is from an interested party . . . it must be corroborated.[152]

D. Unjust Enrichment Under New York Law

Under New York law, a plaintiff seeking relief under a theory of unjust enrichment must show "(1) that the defendant benefitted; (2) at the plaintiff's expense; and (3) that equity and good conscience require restitution."[153]

> The theory of unjust enrichment lies as a quasi-contract claim. It is an obligation the law creates in the absence of any agreement. The existence of a valid and enforceable written contract governing a particular subject matter ordinarily precludes recovery in quasi-contract for events arising out of the same subject matter.[154]

An unjust enrichment claim may not impinge upon an area governed by the federal

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[151] *Whitserve, LLC*, 694 F.3d at 2 (citing *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974 (Fed. Cir. 2010)).

[152] *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002) (citations omitted).

[153] *Leibowitz v. Cornell Univ.*, 584 F.3d 487, 509 (2d Cir. 2009).

[154] *Diesel Props S.r.l. v. Greystone Bus. Credit II LLC*, 631 F.3d 42, 54 (2d Cir. 2011) (quotation marks and citations omitted).

patent law. Thus, "[i]n the absence of an incremental benefit conferred, any attempt to obtain a patent-like royalty for the making, using, or selling of a product in the public domain under the rubric of state unjust enrichment law is preempted."[155]

IV. DISCUSSION

A. The '668 Patent Is Anticipated by the FHT-1 Thermometer

The overwhelming strength of BestMed's anticipation argument should be apparent from the detailed recitation of facts provided above. The only issue in contention is whether the FHT-1 meets the deep tissue temperature limitation of the '668 Patent, and, as discussed above, BestMed had probably created a record sufficient to resolve this issue in its favor on summary judgment. With the addition of the evidence adduced at trial, the conclusion of anticipation is inescapable.

In support of its motion for JMOL on anticipation, BestMed points to: (1) the intrinsic evidence; (2) the testimony of Goldberg showing that the source code of the FHT-1 embodies the deep tissue temperature limitation of the FHT-1; (3) the copious pre-litigation documents authored by Medisim stating that its R.A.T.E. technology measures the temperature prevailing under the skin; (4) the

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[155] *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1382 (Fed. Cir. 2005).

absence of evidence marking the shift between the FHT-1 and the supposedly revolutionary FHT-1A; and (5) the contradictory testimony offered by Medisim.[156]

In its opposition, Medisim takes pains to avoid addressing the substance of BestMed's contentions. Medisim begins by arguing that BestMed failed to preserve its right to bring a post-trial motion for JMOL on invalidity by first bringing a motion for JMOL prior to the cases's submission to the jury.[157] I have already ruled that this argument has no merit, and I do so here again, for the same reasons I stated previously.[158]

Medisim's second attempt to avoid confronting the anticipation evidence presented to the jury involves mischaracterizing BestMed's argument for JMOL. Medisim asserts that "BestMed seeks JMOL on anticipation solely on the grounds that the *fixed baseline* of the FHT-1 device is the same as the 'deep tissue

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[156] *See* Def. Mem. at 2-7.

[157] *See* Opp. Mem. at 2 ("BestMed failed to previously move for JMOL on invalidity . . . despite multiple opportunities to do so.").

[158] *See* 3/18/13 Order, Doc. No. 190. BestMed's motion for a new trial is granted, conditioned on an appellate court determining that it failed to preserve its right to bring a post-trial motion for JMOL. In this event, I will then entertain a motion for summary judgment on anticipation prior to the commencement of a new trial. *Cf. ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1326 (Fed. Cir. 2012) ("In remanding for a limited new trial [on literal infringement and obviousness] . . . we do not foreclose the district court from entertaining a motion for summary judgment on these issues that might obviate the need for a further trial.")).

temperature' claimed in the '668 [P]atent. . . ."[159] Of course, this is not BestMed's argument: in fact, BestMed argues that the *intermediate temperature* of the FHT-1 reads on to the 'deep tissue temperature' limitation of the '668 Patent,[160] not that the 'fixed baseline' reads on to the limitation.

The keystone of this argument is the intrinsic evidence. As discussed at length above, the '668 Patent makes it abundantly clear that deep tissue temperature may be derived from the '397 algorithm. Further, there is no dispute that the non-invasive FHT-1 thermometer utilized the '397 algorithm in order to arrive at an intermediate temperature. In fact, Yarden conceded at trial that the FHT-1 thermometer was marked with the '397 Patent.[161] Given these facts, Goldberg's uncontradicted testimony that source code of the FHT-1 thermometer implements the '397 algorithm to arrive at an intermediate temperature constitutes strong evidence of anticipation, particularly when coupled with Yarden's deposition testimony admitting that the FHT-1 uses the '397 algorithm to arrive at an intermediate temperature, and then corrects to core via a third-order

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[159] Opp. Mem. at 3 (emphasis added) (citing Def. Mem. at 2, which makes no mention of the 'fixed baseline').

[160] *See* Def. Mem. at 3 (arguing that "the overwhelming weight of the evidence demonstrates that the *intermediate body temperature* calculated by the prior art FHT-1 was a deep tissue temperature.").

[161] *See* Tr. (Yarden Cross) at 271:19-22.

polynomial.[162]

Medisim's pre-litigation descriptions of its R.A.T.E. technology corroborate Goldberg's anticipation conclusion. As I must, I fully credit the jury's implicit finding that Yarden's self-interested testimony distinguishing "deep tissue temperature" from "deep tissues' temperature" was convincing. I also fully credit the jury's implicit finding that some of Medisim's contemporaneous marketing documents mistook deep tissue temperature for core temperature, or vice versa.

Nevertheless, the uncontroverted fact is that, in the process of pitching its thermometers to BestMed, Medisim represented that its R.A.T.E. technology calculated "the temperature existing under the skin[,]"[163] a phrase that the parties agree corresponds to deep tissue temperature.[164] Indeed, as BestMed points out,[165] Medisim's pre-litigation characterization of R.A.T.E. technology reads on to the

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[162] *See id*. (Goldberg Redirect) at 1398:13-1399:18 (discussing Yarden's deposition testimony while it was displayed to the jury).

[163] DX-TK at K-J 01803.

[164] Medisim cavils that "BestMed['s] sole attempt[] to link DTX-TK to the FHT-1 device is based upon Mr. Cohen's testimony that Medisim did not advise Mr. Cohen that the technology of DTX-TK is 'not going to be used' or 'was not found' in the forthcoming FHT-1 device." Opp. Mem. at 5 n.7. Given that DTX-TK is a marketing document used by Medisim in the process of pitching the FHT-1 to BestMed, and the fact that BestMed began selling the FHT-1 shortly thereafter, this argument is not convincing. More to the point, it is not evidence.

[165] *See* Reply Mem. at 3.

deep tissue limitation of the '668 Patent almost word-for-word.[166] In short, because the underlying physical process described by Medisim's marketing documents corresponds to the deep tissue temperature limitation, a reasonable jury would necessarily find these documents corroborative of anticipation.

Finally, the absence of contemporaneous evidence marking the switch from the FHT-1 to the FHT-1A, as well as the absence of evidence that the source code of the FHT-1A differed from that of the FHT-1, provide additional support for finding anticipation. The only evidence offered by Medisim that it notified BestMed of the switch to the FHT-1A consists of one cryptic e-mail, which does not reference any new technology, and Yarden's unsupported assertion that somebody at Medisim kept BestMed apprised of the innovation of the FHT-1A.

Of course, "'conclusory assertions . . . do 'not show the existence of a genuine issue of fact to be tried.'"[167] Moreover, even if Yarden's unsupported assertion that some unnamed person at Medisim informed BestMed of the new

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[166] *Compare* DX-TK at K-J 01803 ("a calculation [is] performed of the temperature existing in the blood vessels under the skin at that moment, which causes the measured flow") *with* '668 Patent at col. 13:15 ("to calculate[] a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors").

[167] *Morales v. Rooney*, Nos. 10 Civ. 1692, 10 Civ. 1702, 2013 WL 322784, at *1 (2d Cir. Jan. 29, 2013) (quoting *Major League Baseball Props., Inc. v. Salvino*, Inc., 542 F.3d 290, 310 (2d Cir. 2008)).

technology supposedly embodied in the FHT-1A is credited, the complete absence of evidence relating to the FHT-1A's internal operations and its impact on BestMed's sales, as well as the uncontradicted evidence that Medisim did not ask BestMed to mark the FHT-1A patent-pending, corroborate a finding of anticipation.

The evidence presented by Medisim does nothing to disturb the conclusion that a reasonable jury would necessarily have found anticipation. Because Medisim's principal strategy lay in mischaracterizing BestMed's argument, its argument in opposition to BestMed's *actual* argument is relegated to a footnote.[168] In this footnote, Medisim advances the conclusory testimony of Yarden and Lipson, upon which no reasonable juror could have relied.[169]

One problem common to both Lipson and Yarden's testimony is that, while both offer conclusory denials that the intermediate temperature of the FHT-1 is a deep tissue temperature, neither provides a convincing account of what the intermediate temperature actually *is*. Lipson's conclusion on this limitation

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[168] *See* Opp. Mem. at 4 n.5 ("Both Mr. Yarden and Dr. Lipson further testified that the output of the heat flux algorithm of the '397 patent practiced by the FHT-1 device (T_{avg}) does not calculate deep tissue temperature.") (citing (Tr. (Yarden Cross) at 267:12-22; *id*. (Goldberg Rebuttal) at1524:6-19)).

[169] *See Whitserve, LLC*, 694 F.3d at 23 (reversing denial of JMOL of anticipation where patentee's expert merely offered conclusory testimony).

appears to be entirely based on placing the FHT-1 in test-mode, applying it to his temple, and comparing its display temperature at equilibrium to the "number that comes out of [the] equation," provided to him by Yarden, "that is the final one used [by the FHT-1] for the prediction of temperature. . . ."[170] Because the "number that comes out of the equation" was 92°F, and the measured temperature of his forehead when the FHT-1 was used in test-mode was 95°F, Lipson concluded that the FHT-1 does not measure a deep tissue temperature.[171]

Even if the jury managed to follow Lipson's theory, this testimony provides no basis for a finding of no anticipation. Lipson's account of his test did not mention its reliability, accuracy, acceptance in the field, or, generally, make any attempt to persuade a reasonable juror that it was a method capable of determining whether a device calculated deep tissue temperature. Based on Medisim's description of Lipson's test in its opposition to the present motion,[172] what Lipson had in mind was apparently that the thermo-equilibrium of his temple when measured using the FHT-1 in test mode was his deep tissue temperature, which differed from the undisclosed algorithm for calculating an intermediate

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170 Tr. (Lipson Rebuttal) at 1521:14-1522:4.

171 *Id*.

172 *See* Opp. Mem. at 5-6

temperature that he allegedly received from Yarden.

Notably, this is the *exact* test that I excluded Lipson from relying on in my *Daubert* ruling, on the basis that the thermo-eqilibrium temperature at the skin's surface is not equivalent to deep tissue temperature. For the same reason, his self-test cannot support the jury's verdict of no anticipation.[173] Moreover, even ignoring Lipson's flawed assumption that the FHT-1 used in test-mode could measure deep-tissue temperature, his conclusory account of the undisclosed algorithm provided to him by Yarden mandates a finding that his conclusion of no anticipation has no weight. Finally, it is noteworthy that Lipson *also* testified that calculating a deep tissue temperature when applied to the forehead, using an algorithm developed for an invasive thermometer (*i.e.*, the '397 algorithm), was "essentially what the FHT-1 did."[174]

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[173] *See Daubert*, 509 U.S. at 596 ("[I]n the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment. . . ."). *Accord In re Joint Eastern & Southern District Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995) ("The 'admissibility' and 'sufficiency' of scientific evidence necessitate different inquiries and involve different stakes. Admissibility entails a threshold inquiry over whether a certain piece of evidence ought to be admitted at trial. The *Daubert* opinion was primarily about admissibility. It focused on district courts' role in evaluating the methodology and the applicability of contested scientific evidence in admissibility decisions.") (citations omitted).

[174] Tr. (Lipson Rebuttal Cross) at 1536:5-17.

Likewise, no reasonable jury could have relied upon Yarden's contradictory testimony in finding no anticipation. Yarden's conclusion that the FHT-1 does not calculate a deep tissue temperature appears to be based on his unsupported testimony that, in the Appendix, T_{avg} is inputted into a polynomial formula in order to arrive at deep tissue temperature, and then the time-dependent parameters of temperature change (and one constant) are added to the result to correct to core.

As an initial matter, I note that "an inventor's subjective understanding of patent terminology is *irrelevant* to claim construction. . . ."[175] The reason for this rule is obvious: because the *quid pro quo* of receiving patent protection is public disclosure, an inventor's undisclosed thoughts have no bearing on construing a patent. Additionally, the inventor of a patent has every incentive to stretch the truth, further reducing the probative value of his uncorroborated testimony about his invention.

Although Yarden's unsupported testimony did not come in the context of *Markman* proceedings, it nevertheless falls within the scope of this rule, as his professed understanding of the Appendix is purely subjective. Yarden's testimony

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[175] *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1321-22 (Fed. Cir. 2012) (emphasis added) (citing *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346-47 (Fed. Cir. 2008)).

is contradicted by the '668 Patent specification, which establishes that the output of the '397 algorithm is deep tissue temperature, while the entirety of the formula disclosed in the Appendix corrects to core.[176] It is also contradicted by Yarden's own deposition, in which he stated that the FHT-1 uses a third-order polynomial to correct to core.[177] In fact, even counsel for Medisim appear to have believed that

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[176] *See, e.g.* '668 Patent at col. 1:55-2:2 ("These temperature changes may be used to rapidly compute a deep tissue temperature of the body, using a heat flux calculation similar to that described in the ['397 Patent][,] for example."); *id.* at col. 2:6-11 ("The thermometer is configured to perform the heat flux calculation so as to derive a value of the local temperature. The local temperature, together with the temperature measurements and the time dependent parameters of temperature change may then be used to calculate a core body temperature."); *id.* at col. 7:1-17 ("The local temperature determined by the '397 algorithm is less affected than the surface temperature at the measurement site is to external factors such as ambient temperature and humidity. . . . In order to determine the core body temperature, processing unit 36 computes and applies an empirically-determined formula, which is described in detail in an Appendix herein below. The formula is based on fitting a linear equation comprising several temperature-related parameters to clinically measured values of core body temperature. The temperature related parameters include sensor temperature readings, time-dependent temperature rates of change, *and the value of local body temperature determined by the '397 algorithm*.") (emphasis added); *id.* at col. 12:43-49 ("wherein calculating the deep tissue temperature comprises estimating the deep tissue temperature by solving a time dependent heat conduction transfer equation, and wherein correcting for the difference between the core body temperature and the deep tissue temperature comprises computing a polynomial function of the deep tissue temperature.").

[177] *See* Goldberg Redirect at 1398:13-1399:18 (discussing the portion of Yarden's deposition that BestMed cited in opposition to Medisim's motion for summary judgment of no inequitable conduct, and pointing out the similarity between Yarden's description of the FHT-1 and the '668 Patent).

the formula disclosed in the Appendix described correcting to core.[178] In short, Yarden's unsupported, self-serving, and subjective characterization of the '668 Patent provides a legally insufficient basis for the jury's finding of no anticipation. Moreover, even if it could be credited, it still would not alter the necessary conclusion of no anticipation, because, as discussed above, the FHT-1 indisputably employs a third-order polynomial of the sort that Yarden claims is necessary for arriving at a deep tissue temperature.

For all these reasons, BestMed's motion for JMOL on anticipation is granted. The prior-art FHT-1 device meets the deep tissue temperature limitation of, and therefore anticipates, the '668 Patent. Because I direct JMOL on anticipation, I need not consider the parties' contentions on obviousness,

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[178] *See* Tr. (Medisim Opening Statement) at 57:8-13 ("For the FHT-1, you take the measurement and you directly calculate [an] approximation of core body temperature; whereas, . . . the '668 patent requires the two step process. You *directly measure* local or deep tissue temperature, and you correct in order to receive the core body temperature."). Counsel for Medisim altered this formulation during summations in a telling manner. *See id*. (Medisim Summation) at 1645:4-9 ("The '668 patent requires two steps: You measure *directly calculating* local deep tissue and then you correct to achieve an approximation of core. The FHT-1 is a one-step process, it directly takes you to core. It takes measurements and directly calculates an approximation of core body temperature."). What, if anything, "directly calculating" a value entails was left obscure. Needless to say, no reasonable jury could have found no anticipation based on the unsupported distinction between a "direct[]" calculation and an indirect calculation, particularly in light of undisputed evidence showing that the FHT-1 calculates an intermediate temperature using the '397 algorithm.

infringement, willful infringement, or patent damages.

B. Unjust Enrichment[179]

There is no evidence in the record to support the jury's award of damages to Medisim for unjust enrichment. The jury found against Medisim on its unfair competition claim, and was instructed that it could only find unjust enrichment based upon BestMed's sales of the accused products. To the extent that BestMed's sales of the accused products occurred during the operation of the IDA and the PSA, any claim for unjust enrichment is waived by those contracts.[180] Thus, the jury's verdict of unjust enrichment was grounded solely on BestMed's sales of the accused products subsequent to the termination of the PSA on May 1, 2009.

In light of my holding that the '668 Patent is invalid, and the jury's

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[179] I have considered, and reject Medisim's arguments that: (1) BestMed failed to preserve its motion for JMOL on unjust enrichment; and (2) BestMed's JMOL for unjust enrichment is an improper attempt to raise a Rule 12(b)(6) motion post-trial. *See* Opp. Mem. at 2-3; 23 n.30. *First*, BestMed moved for JMOL on unjust enrichment prior to the case's submission to the jury. *See* Tr. (JMOL Conference) at 1238:5-6. *Second*, BestMed's argument is that there is insufficient evidence to support the jury's verdict on unjust enrichment in light of the IDA and PSA, and the jury's verdict on unfair competition. This is a far cry from an untimely motion under Rule 12(b)(6).

[180] Medisim acknowledges that a claim for unjust enrichment that accrued during the IDA or PSA is waived, and argues that its claim for unjust enrichment accrued "when [BestMed] began selling the competing K-Jump device after the termination of both the IDA and PSA." Opp. Mem. at 23.

verdict of no unfair competition, an unjust enrichment claim cannot arise out of BestMed's sales of the accused products subsequent to the expiration of the PSA. Prior to the end of the PSA, Yarden applied for the '668 Patent, in hopes of receiving a limited monopoly in exchange for disclosing his invention to the public. Now that Medisim's attempt to gain a monopoly through the patent law has proved unavailing, it cannot argue that it should nevertheless receive the same protection through the state law of unjust enrichment.[181] A quasi-contract granting Medisim patent-like protection over its invalidated patent would usurp the federal patent law, and for this reason, the jury's verdict on unjust enrichment must be overturned.

Moreover, even if the '668 Patent were valid, there would be no basis in the record for the jury's award of damages on unjust enrichment, because there was no evidence to support a finding that BestMed received an incremental benefit over that compensable by the patent laws. Medisim did not present any evidence differentiating between patent damages and non-patent damages, instead relying

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[181] *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152-59 (1989) (holding that unpatentable subject matter, *e.g.*, an invalidated patent, passes to the public to freely use). *See also University of Colorado Found., Inc. v. American Cyanamid Co.*, 342 F.3d 1298, 1307 (Fed. Cir. 2003).

upon BestMed's profits from all of the accused products.[182] In its opposition brief, Medisim asserts that BestMed attained an incremental benefit over the benefit compensable through the patent law by its "misappropriat[ing] goodwill, improper[ly] us[ing] [] confidential know-how, and exploiting Medisim's information to start new customer relationships[,]"[183] but the only *evidence* it presents in support of this assertion relates to a single new customer of BestMed's, Kroger, who purchased the FHT-1 thermometer during the operation of the IDA.[184] For these reasons, I grant BestMed's motion for JMOL on unjust enrichment.

C. Medisim's Pending Motions

The following post-trial motions brought by Medisim are denied as moot as a result of the foregoing: (1) its motion for a judicial finding of willful infringement; (2) its motion for a permanent injunction enjoining BestMed from

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[182] *See* Tr. (Cross-Examination of Andrew Carter) at 995:23-996:9 ("A. Honestly, I don't know what non-patent claims are still in the case. I focused my work generally on the patent side. And on the non-patent side, [a] year and a half ago I calculated the profit on the BestMed units, and that's it. Q. Through this theory, this disgorgement theory of the non-patent damages, is that right? A. It's the profit of — it's the profit BestMed makes on its products, under whatever theory it comes in. I'm not trying to tie it off anyway. Again, I focused on the patent side, I merely calculated a profit number for the BestMed products. That's what I'm doing. I didn't get into all those other claims.").

[183] Opp. Mem. at 24 (citations omitted).

[184] *See* Tr. (Cohen Cross) at 706:1-9.

continuing its supposedly infringing activities; (3) its motion for interest and costs; and (4) its motion for an accounting of BestMed's pre-injunction sales and for supplemental damages.

Medisim's motion for sanctions and attorneys' fees is denied. Both parties engaged in 'zealous advocacy' throughout the case, and there is simply no basis in law or equity for exacting these extraordinary remedies on BestMed.

This leaves Medisim's motion for an injunction disposing of BestMed's infringing IFUs. Title 17 of the United States Code, Section 503(b) provides that a court may order

> [T]he destruction or other reasonable disposition of all copies . . . found to have been made or used in violation of the copyright owner's exclusive rights, and of all plates, molds, matrices, masters, tapes, film negatives, or other articles by means of which such copies or phonorecords may be reproduced.

As Medisim points out, it lacks a remedy at law for its copyright claim, leaving equitable relief as the sole remedy for enforcing its copyright.[185] For this reason, and because BestMed has not contested Medisim's right to equitable relief on its copyright claim despite having the opportunity to do so, Medisim's motion for a

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[185] Memorandum in Support of Motion for a Permanent Injunction and an Order for Disposition of Infringing Materials, Doc. No. 181, at 11 ("'An order directing impoundment or forfeiture is appropriate only where legal remedies or statutory damages do not provide adequate relief.'") (quoting *Software Freedom Conservancy, Inc. v. Best Buy Co.*, No. 09 Civ. 10155, 2010 WL 2985320, at *4 (S.D.N.Y. July 27, 2010)).

disposition of materials infringing its copyright is granted.

V. CONCLUSION

For the foregoing reasons, BestMed's motion for JMOL is granted. I hold that the '668 Patent is invalid as anticipated by the FHT-1 thermometer, and likewise overturn the jury's verdict for Medisim on its unjust enrichment claim.

Medisim's post-trial motions are denied, except for its motion for an injunction disposing of materials in BestMed's possession infringing its copyright, which is granted. BestMed is ordered to deliver all such infringing materials to Medisim within thirty days of this Order.

The Clerk of the Court is directed to close Doc. Nos. 130, 152, 177, 184, and 187. The Judgment entered at Doc. No. 156 is hereby vacated. The Judgment Clerk is directed to enter a new judgment consistent with this Order.

SO ORDERED:

Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
May 15, 2013

- Appearances -

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ADDENDUM 5

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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MEDISIM LTD.,

Plaintiff,

-against-

BESTMED LLC,

Defendant.

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10 **CIVIL** 2463 (SAS)

JUDGMENT

Whereas this case was tried to a jury, which returned a verdict finding that defendant BestMed LLC ("BestMed") willfully infringed on U.S. Patent No. 7,597,668 ("the '688 Patent"), of which plaintiff Medisim Ltd. ("Medisim") is the sole assignee and owner; the jury also having found that BestMed infringed Medisim's copyright in the Instructions for Use ("IFU") for its thermometers, and that BestMed was unjustly enriched under New York law; the jury having awarded Medisim $1.2 million for its patent infringement claim, and $2.29 million for its unjust enrichment claim; Medisim having sought only equitable relief for its copyright claim; post-trial, BestMed having moved for judgment as a matter of law ("JMOL"), or, alternatively, for a new trial, and the matter having come before the Honorable Shira A. Scheindlin, United States District Judge, and the Court, on May 15, 2013, having rendered its Opinion and Order granting BestMed's motion for JMOL, holding that the '668 Patent is invalid as anticipated by the FHT-1 thermometer, and likewise overturning the jury's verdict for Medisim on its unjust enrichment claim, denying Medisim's post-trial motions, except for its motion for an injunction disposing of materials in BestMed's possession infringing its copyright, which is granted, ordering BestMed to deliver all such infringing materials to Medisim within thirty days of this Order, vacating the Judgment entered at Doc. No. 156, and directing the Judgment Clerk to enter a new judgment consistent with this

Order, it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Opinion and Order dated May 15, 2013, BestMed's motion for JMOL is granted; the Court holds that the '668 Patent is invalid as anticipated by the FHT-1 thermometer, and likewise overturn the jury's verdict for Medisim on its unjust enrichment claim; Medisim's post-trial motions are denied, except for its motion for an injunction disposing of materials in BestMed's possession infringing its copyright, which is granted; BestMed is ordered to deliver all such infringing materials to Medisim within thirty days of the Order dated May 15, 2013.

Dated: New York, New York
May 21, 2013

RUBY J. KRAJICK

Clerk of Court

BY: _____

Deputy Clerk

THIS DOCUMENT WAS ENTERED ON THE DOCKET ON _____

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

Date:

In Re:

-v-

Case #: ( )

Dear Litigant,

Enclosed is a copy of the judgment entered in your case.

Your attention is directed to Rule 4(a)(1) of the Federal Rules of Appellate Procedure, which requires that if you wish to appeal the judgment in your case, you must file a notice of appeal within 30 days of the date of entry of the judgment (60 days if the United States or an officer or agency of the United States is a party).

If you wish to appeal the judgment but for any reason you are unable to file your notice of appeal within the required time, you may make a motion for an extension of time in accordance with the provision of Fed. R. App. P. 4(a)(5). That rule requires you to show "excusable neglect" or "good cause" for your failure to file your notice of appeal within the time allowed. Any such motion must first be served upon the other parties and then filed with the Pro Se Office no later than 60 days from the date of entry of the judgment (90 days if the United States or an officer or agency of the United States is a party).

The enclosed Forms 1, 2 and 3 cover some common situations, and you may choose to use one of them if appropriate to your circumstances.

The Filing fee for a notice of appeal is $5.00 and the appellate docketing fee is $450.00 payable to the "Clerk of the Court, USDC, SDNY" by certified check, money order or cash. **No personal checks are accepted.**

Ruby J. Krajick, Clerk of Court

by: _____

, Deputy Clerk

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

----------X

-V-

NOTICE OF APPEAL

civ. ( )

----------X

Notice is hereby given that _____ (party) hereby appeals to the United States Court of Appeals for the Second Circuit from the Judgment [describe it]

entered in this action on the _____ (day) day of _____ (month), _____ (year).

_____
(Signature)

_____
(Address)

_____
(City, State and Zip Code)

Date: _____ ( ) _____ - _____
(Telephone Number)

Note: You may use this form to take an appeal provided that it is received by the office of the Clerk of the District Court within 30 days of the date on which the judgment was entered (60 days if the United States or an officer or agency of the United States is a party).

FORM 1

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

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-V-

MOTION FOR EXTENSION OF TIME TO FILE A NOTICE OF APPEAL

civ. ( )

----------X

Pursuant to Fed. R. App. P. 4(a)(5), _____ respectfully
(party)

requests leave to file the within notice of appeal out of time. _____
(party)

desires to appeal the judgment in this action entered on _____ but failed to file a
(day)

notice of appeal within the required number of days because:

[Explain here the "excusable neglect" or "good cause" which led to your failure to file a notice of appeal within the required number of days.]

_____
(Signature)

_____
(Address)

_____
(City, State and Zip Code)

Date: _____ ( ) _____-_____
(Telephone Number)

Note: You may use this form, together with a copy of Form 1, if you are seeking to appeal a judgment and did not file a copy of Form 1 within the required time. If you follow this procedure, these forms must be received in the office of the Clerk of the District Court no later than 60 days of the date which the judgment was entered (90 days if the United States or an officer or agency of the United States is a party).

District Court will receive it within the 30 days of the date on which the judgment was entered (60 days if the United States or an officer or agency of the United States is a party).

FORM 3

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

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-V-

AFFIRMATION OF SERVICE

civ. ( )

----------X

I, _____, declare under penalty of perjury that I have served a copy of the attached _____

_____

upon _____

_____

whose address is: _____

_____

Date: _____
New York, New York

_____
(Signature)

_____
(Address)

_____
(City, State and Zip Code)

FORM 4

APPEAL FORMS

FORM 2

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

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-V-

NOTICE OF APPEAL
AND
MOTION FOR EXTENSION OF TIME

civ. ( )

----------X

1. Notice is hereby given that _____ hereby appeals to
(party)
the United States Court of Appeals for the Second Circuit from the judgment entered on _____.
[Give a description of the judgment]

2. In the event that this form was not received in the Clerk's office within the required time

_____ respectfully requests the court to grant an extension of time in
(party)
accordance with Fed. R. App. P. 4(a)(5).

a. In support of this request, _____ states that
(party)
this Court's judgment was received on _____ and that this form was mailed to the
(date)
court on _____.
(date)

_____
(Signature)

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(Address)

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(City, State and Zip Code)

Date: _____ ( ) _____ - _____
(Telephone Number)

Note: You may use this form if you are mailing your notice of appeal and are not sure the Clerk of the

ADDENDUM 6

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDISIM LTD., Plaintiff, -v- BESTMED, LLC, Defendant.	10-CV-2463 (SAS) (RLE)
	[PROPOSED] ORDER AMENDING THE CLERK'S JUDGMENT

THIS MATTER having been brought to the Court by Plaintiff Medisim Ltd. ("Medisim") upon Medisim's Motion to Amend the Clerk's Judgment entered on May 21, 2013 [D.E. 211], and the Court having considered the submissions of the parties in support of and in opposition to Medisim's motion, and the Court having considered the arguments of counsel, and for other good cause having been shown,

IT IS ON THIS 6 day of June, 2013,

ORDERED that Medisim's Motion to Amend the Clerk's Judgment filed on June 4, 2013 be and hereby is **GRANTED**; and it is further

ORDERED that the Clerk's Judgment [D.E. 211] shall be amended to state that only claims 1, 8-12, 15, 19, 21, 27, 32 and 35-37 of U.S. Patent No. 7,597,668 ("the '668 patent") are invalid as anticipated by the FHT-1 thermometer; and it is further

ORDERED that the Clerk is directed to enter an amended judgment which indicates that U.S. Patent No. 7,597,668 shall be referred to as "the '668 patent"; and it is further

ORDERED that the Clerk is directed to enter an amended judgment in accordance with this Order.

The clerk of the Court is directed to close the motion (Doc. No. 212).

ME1 15738993v.1

Honorable Shira A. Scheindlin, U.S.D.J.

ADDENDUM 7

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

MEDISIM LTD.,

Plaintiff,

-against-

BESTMED LLC,

Defendant.

----------X

10 **CIVIL** 2463 (SAS)

AMENDED

JUDGMENT

Whereas this case was tried to a jury, which returned a verdict finding that defendant BestMed LLC ("BestMed") willfully infringed on U.S. Patent No. 7,597,668 ("the '688 Patent"), of which plaintiff Medisim Ltd. ("Medisim") is the sole assignee and owner; the jury also having found that BestMed infringed Medisim's copyright in the Instructions for Use ("IFU") for its thermometers, and that BestMed was unjustly enriched under New York law; the jury having awarded Medisim $1.2 million for its patent infringement claim, and $2.29 million for its unjust enrichment claim; Medisim having sought only equitable relief for its copyright claim; post-trial, BestMed having moved for judgment as a matter of law ("JMOL"), or, alternatively, for a new trial; the Court, on May 15, 2013, having rendered its Opinion and Order granting BestMed's motion for JMOL, holding that the '668 Patent is invalid as anticipated by the FHT-1 thermometer, and likewise overturning the jury's verdict for Medisim on its unjust enrichment claim, denying Medisim's post-trial motions, except for its motion for an injunction disposing of materials in BestMed's possession infringing its copyright, which is granted, ordering BestMed to deliver all such infringing materials to Medisim within thirty days of this Order, vacating the Judgment entered at Doc. No. 156, and directing the Judgment Clerk to enter a new judgment consistent with this Order; thereafter, Medisim having moved to amend the Clerk's Judgment, and the matter having

come before the Honorable Shira A. Scheindlin, United States District Judge, and the Court, on June 6, 2013, having rendered its Order granting Medisim's Motion to Amend the Clerk's Judgment filed on June 4, 2013, that the Clerk's Judgment [D.E. 211] shall be amended to state that only claims 1, 8-12, 15, 19, 21, 27, 32 and 35-37 of U.S. Patent No. 7,597,668 ("the '668 patent") are invalid as anticipated by the FHT-1 thermometer, directing the Clerk to enter an amended judgment which indicates that U.S. Patent No. 7,597,668 shall be referred to as "the '668 patent", and directing the Clerk to enter an amended judgment in accordance with this Order, it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Opinion and Order dated May 15, 2013 and Order dated June 6, 2013, BestMed's motion for JMOL is granted; U.S. Patent No. 7,597,668 shall be referred to as "the '668 patent"; the Court holds that only claims 1, 8-12, 15, 19, 21, 27, 32 and 35-37 of U.S. Patent No. 7,597,668 ("the '668 patent") are invalid as anticipated by the FHT-1 thermometer, and likewise overturn the jury's verdict for Medisim on its unjust enrichment claim; Medisim's post-trial motions are denied, except for its motion for an injunction disposing of materials in BestMed's possession infringing its copyright, which is granted; BestMed is ordered to deliver all such infringing materials to Medisim within thirty days of the Order dated May 15, 2013.

Dated: New York, New York
June 11, 2013

RUBY J. KRAJICK

Clerk of Court

BY: _____

Deputy Clerk

THIS DOCUMENT WAS ENTERED
ON THE DOCKET ON _____

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

Date:

In Re:

-v-

Case #: ( )

Dear Litigant,

Enclosed is a copy of the judgment entered in your case.

Your attention is directed to Rule 4(a)(1) of the Federal Rules of Appellate Procedure, which requires that if you wish to appeal the judgment in your case, you must file a notice of appeal within 30 days of the date of entry of the judgment (60 days if the United States or an officer or agency of the United States is a party).

If you wish to appeal the judgment but for any reason you are unable to file your notice of appeal within the required time, you may make a motion for an extension of time in accordance with the provision of Fed. R. App. P. 4(a)(5). That rule requires you to show "excusable neglect" or "good cause" for your failure to file your notice of appeal within the time allowed. Any such motion must first be served upon the other parties and then filed with the Pro Se Office no later than 60 days from the date of entry of the judgment (90 days if the United States or an officer or agency of the United States is a party).

The enclosed Forms 1, 2 and 3 cover some common situations, and you may choose to use one of them if appropriate to your circumstances.

The Filing fee for a notice of appeal is $5.00 and the appellate docketing fee is $450.00 payable to the "Clerk of the Court, USDC, SDNY" by certified check, money order or cash. **No personal checks are accepted.**

Ruby J. Krajick, Clerk of Court

by: _____
, Deputy Clerk

APPEAL FORMS

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

----------X

-V-

NOTICE OF APPEAL

civ. ( )

----------X

Notice is hereby given that _____ (party)
hereby appeals to the United States Court of Appeals for the Second Circuit from the Judgment [describe it]

entered in this action on the _____ (day) day of _____ (month) , _____ (year) .

_____ (Signature)

_____ (Address)

_____ (City, State and Zip Code)

Date: _____ ( ) _____ - _____ (Telephone Number)

Note: You may use this form to take an appeal provided that it is received by the office of the Clerk of the District Court within 30 days of the date on which the judgment was entered (60 days if the United States or an officer or agency of the United States is a party).

FORM 1

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

----------X

-V-

MOTION FOR EXTENSION OF TIME TO FILE A NOTICE OF APPEAL

civ. ( )

----------X

Pursuant to Fed. R. App. P. 4(a)(5), _____ respectfully
(party)

requests leave to file the within notice of appeal out of time.

_____
(party)

desires to appeal the judgment in this action entered on _____ but failed to file a
(day)

notice of appeal within the required number of days because:

[Explain here the "excusable neglect" or "good cause" which led to your failure to file a notice of appeal within the required number of days.]

_____
(Signature)

_____
(Address)

_____
(City, State and Zip Code)

Date: _____ ( ) _____ - _____
(Telephone Number)

Note: You may use this form, together with a copy of Form 1, if you are seeking to appeal a judgment and did not file a copy of Form 1 within the required time. If you follow this procedure, these forms must be received in the office of the Clerk of the District Court no later than 60 days of the date which the judgment was entered (90 days if the United States or an officer or agency of the United States is a party).

District Court will receive it within the 30 days of the date on which the judgment was entered (60 days if ~~the United States or an officer or agency of the United States is a party).~~

FORM 3

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

---X

-V-

---X

AFFIRMATION OF SERVICE

civ. ( )

I, ______________________________, declare under penalty of perjury that I have

served a copy of the attached ____

____

upon ____

____

whose address is: ____

____

Date: ____________________
New York, New York

____
(Signature)

____
(Address)

____
(City, State and Zip Code)

FORM 4

FORM 2

United States District Court
Southern District of New York
Office of the Clerk
U.S. Courthouse
500 Pearl Street, New York, N.Y. 10007-1213

-V-	**NOTICE OF APPEAL AND MOTION FOR EXTENSION OF TIME**
	civ. ( )

1. Notice is hereby given that ______________________ (party) hereby appeals to the United States Court of Appeals for the Second Circuit from the judgment entered on __________.
[Give a description of the judgment]

2. In the event that this form was not received in the Clerk's office within the required time ______________________ (party) respectfully requests the court to grant an extension of time in accordance with Fed. R. App. P. 4(a)(5).

a. In support of this request, ______________________ (party) states that this Court's judgment was received on ______________ (date) and that this form was mailed to the court on ______________ (date).

____
(Signature)

____
(Address)

____
(City, State and Zip Code)

Date: ______________ ( ) ______-__________
(Telephone Number)

Note: You may use this form if you are mailing your notice of appeal and are not sure the Clerk of the

ADDENDUM 8

US007597668B2

(12) **United States Patent**
Yarden

(10) **Patent No.: US 7,597,668 B2**
(45) **Date of Patent: Oct. 6, 2009**

(54) **NON-INVASIVE TEMPERATURE MEASUREMENT**

(75) Inventor: **Moshe Yarden**, Mevaseret Zion (IL)

(73) Assignee: **Medisim Ltd.**, Airport (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 44 days.

(21) Appl. No.: **11/444,710**

(22) Filed: **May 31, 2006**

(65) **Prior Publication Data**

US 2007/0282218 A1 Dec. 6, 2007

(51) **Int. Cl.**
A61B 5/00 (2006.01)
G01K 3/00 (2006.01)

(52) **U.S. Cl.** **600/549**; 374/102; 374/107; 374/110

(58) **Field of Classification Search** 600/549; 374/112, 142, 100, 101, 107, 110, 113, 120, 374/121, 134, 158
See application file for complete search history.

(56) **References Cited**

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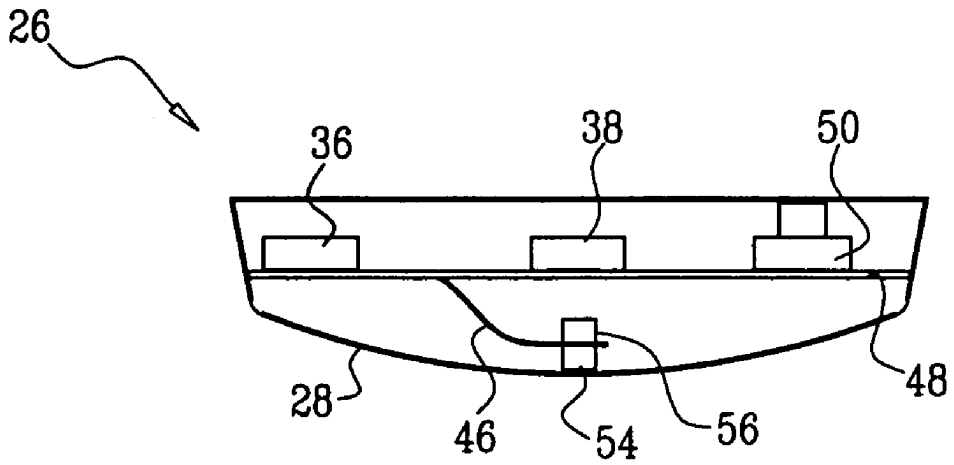
(Continued)

Primary Examiner—Max Hindenburg
Assistant Examiner—Adam J Eiseman
(74) *Attorney, Agent, or Firm*—Abelman, Frayne & Schwab

(57) **ABSTRACT**

A thermometric device includes a probe having a membrane configured to be applied to an external surface of a body of a subject and one or more temperature sensors located within the probe in thermal contact with the membrane. A processing unit is configured to receive temperature readings from the one or more temperature sensors, to determine time-dependent parameters of temperature change responsively to the temperature readings, to calculate a local temperature of the body using a function including the time-dependent parameters, and to calculate a core body temperature by correcting for a difference between the core body temperature and the local temperature.

37 Claims, 2 Drawing Sheets



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"Core temperature measurement: a comparison of axilla, tympanic membrane and pulmonary artery blood temperature", by Fullbrook, Intensive critical care nursing, Oct. 1997. 13(5): 266-272.
U.S. Appl. No. 60/572,651.

* cited by examiner

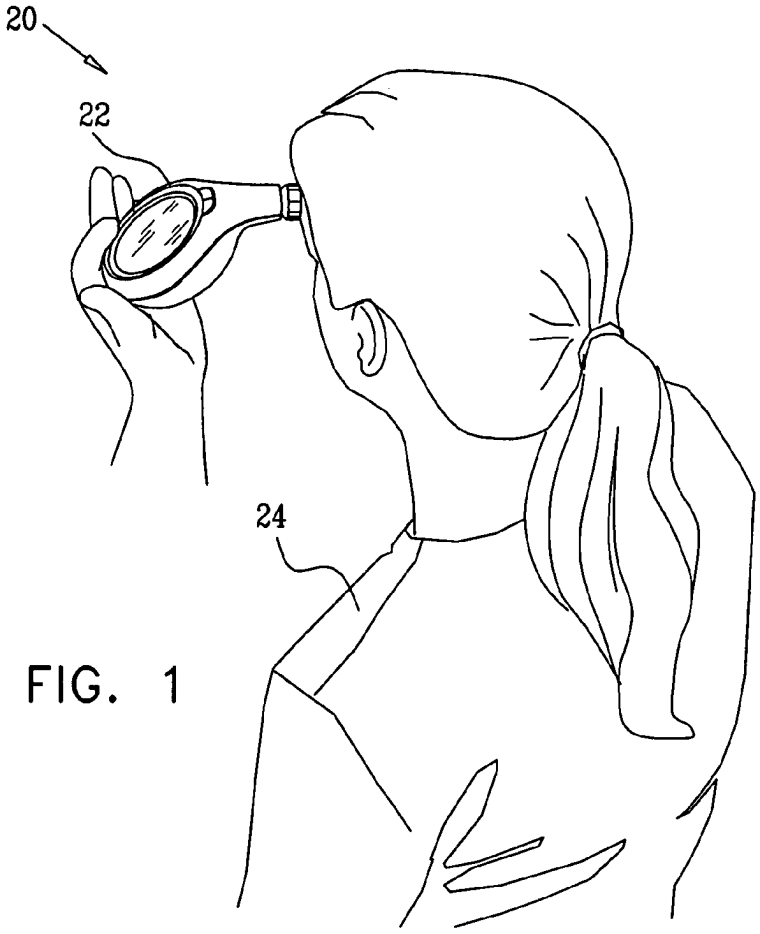


FIG. 1

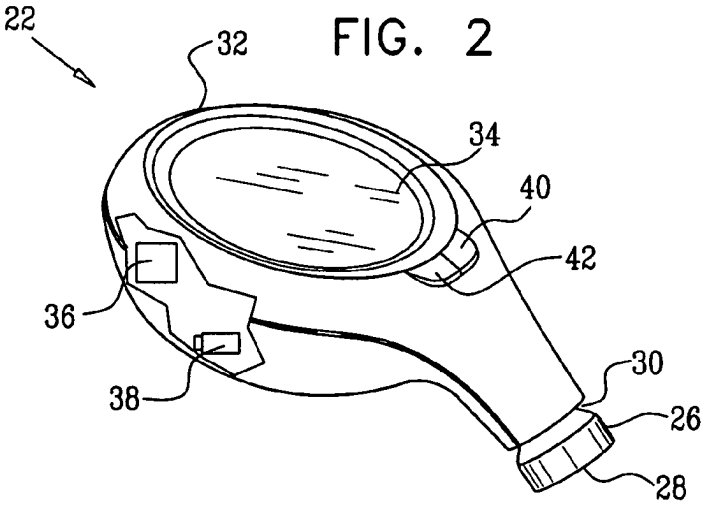


FIG. 2

FIG. 3

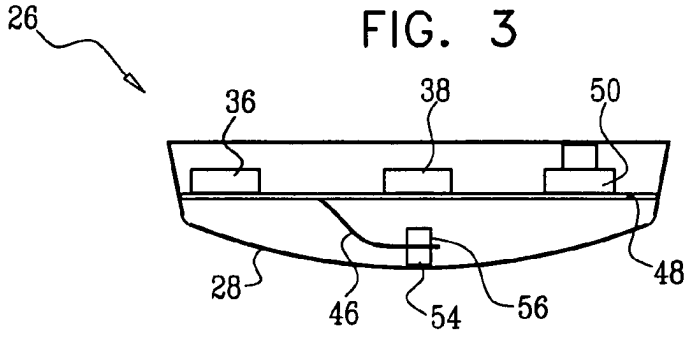


FIG. 4A

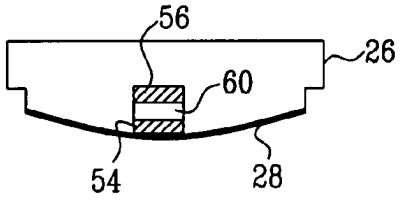


FIG. 4B

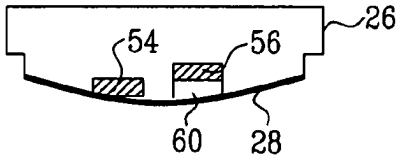


FIG. 4C

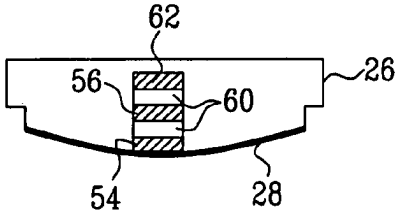


FIG. 4D

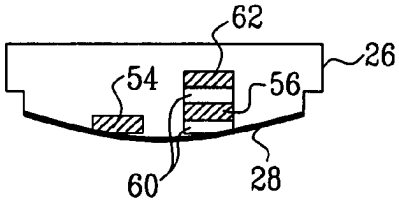


FIG. 4E

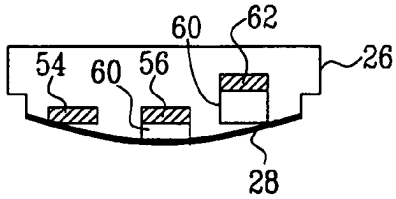
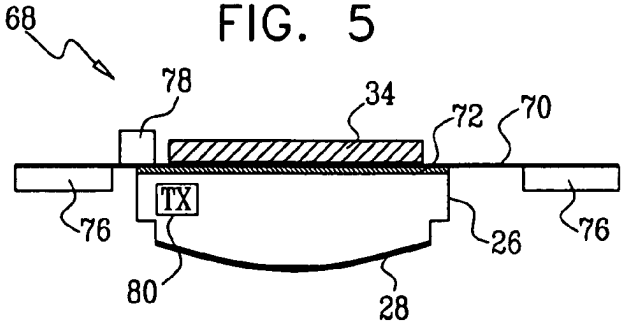


FIG. 5



NON-INVASIVE TEMPERATURE MEASUREMENT

FIELD OF THE INVENTION

The present invention relates generally to health care and specifically to methods and systems for rapid measurement of subject temperature.

BACKGROUND OF THE INVENTION

The measurement of a body temperature is useful for assessing the health of a subject. Typically, a body temperature is measured by a thermometer positioned in a body cavity, such as the mouth, the axilla, or the rectum. A core body temperature, commonly measured in the pulmonary artery, is generally considered a better indicator of a subject's health than peripheral temperatures of the aforementioned body cavities or of external locations, such as the subject's forehead or temple area.

A variety of thermometry devices are used to measure body temperatures. U.S. Pat. No. 6,280,397 to Yarden et al., whose disclosure is incorporated herein by reference, provides a high speed temperature measuring device for measuring an internal body temperature by insertion of the device into a body cavity. A heat conduction transfer equation is solved to determine the internal body temperature.

Insertion of a thermometer into a body cavity is an invasive measurement that generally causes some discomfort to the subject. Invasive measurement may also require the subject's cooperation and adherence to measurement procedures, such as keeping a thermometer tip under the tongue during oral temperature measurement. Non-invasive temperature measurement at an external measurement site, such as a subject's forehead, may be less discomforting and less dependent on subject cooperation. However, a large statistical deviation may exist between the temperature at an external measurement site and the core body temperature.

The poor correlation between external and peripheral temperatures with the core body temperature is described by Fullbrook in "Core temperature measurement: a comparison of axilla, tympanic membrane and pulmonary artery blood temperature," *Intensive Critical Care Nursing*, Oct. 1997, 13(5):266-72, whose disclosure is incorporated herein by reference.

U.S. Pat. No. 6,292,685 to Pompei, whose disclosure is incorporated herein by reference, provides a method of detecting human body temperature by laterally scanning an infra-red (IR) temperature detector across a forehead and providing a peak temperature reading from multiple readings.

SUMMARY OF THE INVENTION

Embodiments of the present invention provide apparatus and methods for determining core body temperature based on temperature measurements at the body surface.

A thermometer configured to make non-invasive body temperature measurements includes a probe with an outer, heat-conducting membrane designed to be placed non-invasively against the skin of a subject. In some embodiments, multiple temperature sensors within the probe provide temperature readings at multiple respective thermal distances from the body surface. The temperature readings may be used to determine time-dependent parameters of temperature changes at the respective thermal distances. These temperature changes may be used to rapidly compute a deep tissue temperature of the body, using a heat flux calculation similar to that

described in the above-mentioned U.S. Pat. No. 6,280,397, for example. The deep tissue temperature, referred to hereinbelow as the local temperature, reflects a temperature at a location under the skin that is the source of heat conducted to the sensors in the probe.

The thermometer is configured to perform the heat flux calculation so as to derive a value of the local temperature. The local temperature, together with the temperature measurements and the time dependent parameters of temperature change may then be used to calculate a core body temperature. The calculation is typically based on an empirically-derived formula based on the aforementioned parameters.

After the core body temperature is determined, the thermometer may display the temperature on a screen built into the thermometer.

The thermometer may be configured as a handheld thermometer that is held against the body surface or as a patch thermometer affixed to the body. The thermometer may include additional features such as a radio transceiver for telemetry purposes and/or a timer for measuring intervals at which medication is provided.

To ensure that the contact between the probe membrane and the skin is maintained at a sufficient and relatively consistent pressure, the probe may be made of a compressible material, such as silicone. A pressure sensor also may be comprised in the probe to sense that a consistent pressure is achieved. A handheld thermometer may also include a flexible joint that compensates for angular movements between the thermometer and the subject.

There is therefore provided, in accordance with an embodiment of the present invention, a thermometric device, including:

a probe, including:

a membrane configured to be applied to an external surface of a body of a subject; and

one or more temperature sensors located within the probe in thermal contact with the membrane; and

a processing unit configured to receive temperature readings from the one or more temperature sensors, to determine time-dependent parameters of temperature change responsively to the temperature readings, to calculate a local temperature of the body using a function including the time-dependent parameters, and to calculate a core body temperature by correcting for a difference between the core body temperature and the local temperature.

Typically, the one or more temperature sensors include a plurality of temperature sensors at differing, respective thermal distances from the membrane, and the processing unit is adapted to process the temperature readings responsively to the different thermal distances in order to calculate the core body temperature.

The plurality of temperature sensors may include at least three temperature sensors, and the processing unit may be configured to select a subset of the temperature sensors and to determine the local temperature of the body responsively to the temperature readings provided by the subset.

In some embodiments, a first of the plurality of temperature sensors has a first thermal sensitivity and a second of the plurality of temperature sensors has a second thermal sensitivity.

An insulating material is generally interposed between at least one of the temperature sensors and the membrane in order to define the differing thermal distances. In some embodiments, the insulating material includes a printed circuit.

In further embodiments, the temperature sensors include a first temperature sensor in proximity to the membrane and a

second temperature sensor stacked on the first temperature sensor so that a thermal distance of the second temperature sensor from the membrane includes the first temperature sensor.

A contour of the membrane may be configured so as to cause skin of the body to conform to the contour.

In some embodiments, the device includes a handheld meter, and the probe is attached by a joint to the handheld meter. The joint may be flexible.

In some embodiments, the probe and processing unit are physically separated. The probe may be compressible. Additionally or alternatively, the device may include a wireless transmitter, for transmitting the temperature readings from the probe to the processing unit.

The device may also include a pressure sensor configured to indicate that an appropriate pressure is applied between the membrane and the external surface of the body.

Typically, the device includes a display, on which is displayed the core body temperature.

In some embodiments, the probe is configured to be affixed to the external surface of the body. In these embodiments, an adhesive material may be used to affix the device to the body. Alternatively or additionally, a timer may be included to measure intervals between administrations of a medication to the subject.

Typically, the processor is operative to calculate the core body temperature responsively to sensing a change in a temperature reading from the one or more temperature sensors.

In one embodiment, the probe includes a pressure sensor, which is adapted to measure a pressure of the probe against the body surface, and the processing unit is operative to use the measured pressure in determining the core body temperature.

There is also provided, in accordance with an embodiment of the present invention, a patient care device, including:

a probe for application to an external surface of a body of a subject, the probe including one or more temperature sensors for determining a temperature of the subject; and

a timer for measuring and indicating intervals between administrations of a medication to the subject.

There is further provided a method for thermometric measurement, including:

applying a probe, which includes a heat-conducting membrane and one or more temperature sensors in thermal communication with the membrane, to an external surface of a body of a subject;

receiving temperature readings from the one or more temperature sensors while the probe is applied to the surface of the body;

determining time-dependent parameters of temperature change responsively to the temperature readings;

calculating a local temperature of the body using a function including the time-dependent parameters; and

calculating a core body temperature by correcting for a difference between the core body temperature and the local temperature.

Typically, the one or more temperature sensors include a plurality of temperature sensors at differing, respective thermal distances from the membrane, and calculating the local and core body temperatures includes processing the temperature readings responsively to the different thermal distances in order to calculate the core body temperature.

When the plurality of temperature sensors includes at least three temperature sensors, calculating the local temperature of the body may include selecting a subset of the temperature sensors and calculating the local temperature responsively to the temperature readings provided by the subset.

In some embodiments, applying the probe includes indicating that an appropriate pressure is applied between the membrane and the external surface of the body in order to receive the temperature readings.

Applying the probe may include using an adhesive patch to affix the probe to the body. In some embodiments, the method includes transmitting the temperature of the body from the probe to a telemetry receiver. The method may also include measuring intervals, using the probe, between administrations of a medication to the subject.

Calculating the core body temperature may include determining the core body temperature responsively to sensing a change in a temperature reading from the one or more temperature sensors.

Alternatively, calculating the core body temperature may include determining the core body temperature responsively to sensing a pressure change on the membrane.

In some embodiments, the method includes using a pressure measurement to correct for a difference between the core body temperature and the local temperature.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic, pictorial illustration of a system for non-invasive body temperature measurement using a handheld thermometer, in accordance with an embodiment of the present invention;

FIG. **2** is a schematic, pictorial illustration of a handheld thermometer, in accordance with an embodiment of the present invention;

FIG. **3** is a schematic, cut-away side view of a temperature probe, in accordance with an embodiment of the present invention;

FIGS. **4**A-**4**E are schematic, pictorial illustrations of temperature sensors within the temperature probe, in accordance with an embodiment of the present invention; and

FIG. **5** is a schematic, cut-away side view of a patch thermometer, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

In the embodiments of the present invention that are described below, core body temperature is determined based on measurements made at a surface of a body of a subject.

FIG. **1** is a schematic, pictorial illustration of a system **20** in which a thermometric device, such as a thermometer **22**, is used to determine the core body temperature of a subject **24**, in accordance with an embodiment of the present invention. In system **20**, thermometer **22** is a handheld device configured to be held against the forehead of subject **24** for a measurement period that is typically less than six seconds. It is to be understood that the forehead is one of several suitable temperature measurement sites on the body and that thermometer **22** may be configured to operate at other measurement sites, as described further hereinbelow (FIG. **2**).

In alternative embodiments, also described hereinbelow (FIG. **5**), a thermometer for measuring core body temperature may be configured as a patch rather than as a handheld device. Common to both the handheld and patch configurations is a probe **26** comprising multiple temperature sensors, as described further hereinbelow (FIGS. **2**-**4**).

FIG. **2** is a schematic, pictorial illustration of thermometer **22**, in accordance with an embodiment of the present inven-

tion. Thermometer **22** comprises probe **26** to which is affixed a heat conducting membrane **28**. Membrane **28** is designed to be placed against a temperature measurement site on the body of the subject. Typically, membrane **28** has a diameter of 5-25 mm. In some embodiments, the contour of membrane **28** is slightly convex or concave so as to improve the contact between the membrane and the body. When the membrane is concave, having a concave depression of not more than 2 mm, the membrane conforms to slight protrusions or bumps on the body surface. When the membrane is convex, it pushes into the skin. In either case, a consistent thermal contact with the skin is made across the entire surface of the membrane.

Within probe **26** and in close proximity to membrane **28** are temperature sensors described further hereinbelow (FIGS. **3** and **4**).

Probe **26** is attached by a flexible joint **30** to a handheld meter **32**. Due to the flexibility of joint **30**, a good thermal contact may be maintained between membrane **28** and the measurement site even when the handheld meter is not held at an exact right angle to the measurement site. The flexible joint also ensures good thermal contact if the subject moves during the measurement period. In certain embodiments, the joint is also compressible, or comprises a compressible sleeve, which further compensates for any movement of the subject relative to the handheld meter. Additionally or alternatively, probe **26** may itself be compressible or may comprise a compressible sleeve made of silicone.

Handheld meter **32** further comprises a processing unit **36** and a power source, such as a battery **38**. In certain embodiments, handheld meter **32** also comprises one or more manual control buttons, such as a power switch **40** and a mode button **42**, described further hereinbelow. In some alternative embodiments, some or all of the aforementioned elements comprised in handheld meter **32** may be configured within probe **26**. For example, processing unit **36** and battery **38** may be configured within probe **26**, as illustrated below in FIG. **3**.

An operator of thermometer **22**, who may be subject **24** himself or a healthcare giver who applies thermometer **22** to subject **24**, may turn on thermometer **22** by pressing power switch **40**. An indication of power is provided on a screen **34**, which is a thin panel screen, such as a liquid crystal display (LCD) screen. In some embodiments, the operator may also use mode button **42** to set measurement parameters, such as the site at which the temperature measurement is to be made. For example, a list of possible measurement sites, such as forehead, temple, and neck, may appear on screen **34**, and the operator may make a selection from the list.

Processing unit **36** receives temperature readings from temperature sensors comprised in probe **26** and performs a temperature measurement process to determine a core body temperature, as described further hereinbelow. Processing unit **36** may display the determined core body temperature on screen **34**. Processing unit **36** also may signal that the core body temperature has been determined by sounding an audible beep. As described above, the determination typically is made within six seconds of starting the measurement. This period is sufficiently brief to prevent the heat conductance of the thermometer and in particular of membrane **28** from affecting the temperature of at the measurement site.

In a further embodiment, mode switch **42** also activates a timer for measuring intervals between medications. When the timer is activated, screen **34** may display elapsed time in a format of "hours:minutes:seconds." After a desired interval of time has elapsed, processing unit **36** may provide an indication, such as an audible beep. Timing of medication intervals may be utilized to prevent medication overdosing.

FIG. **3** is a schematic, cut-away side view of probe **26**, in accordance with an embodiment of the present invention. Probe **26** comprises two temperature sensors, illustrated in the figure as a first temperature sensor **54**, which is situated in direct thermal contact with membrane **28**, and a second temperature sensor **56**, situated farther away from membrane **28**. Sensors **54** and **56** may be thermistors or Resistance Temperature Detectors (RTDs) or any form of temperature sensor known in the art.

In this embodiment, sensors **54** and **56** are mounted on either side of a printed electronic circuit, such as a flexible circuit **46**. Consequently, sensor **54** is at a thermal distance of zero from membrane **28**, whereas the thermal distance of sensor **56** from membrane **28** comprises both the thickness of flexible circuit **46** and the thickness of sensor **54**. Alternatively, insulating materials other than a printed circuit may be used to provide the thermal distance between sensor **56** and membrane **28**. For example, in an alternative configuration, sensor **56** may be mounted on the same side of sensor **54** but with no direct contact to membrane **28** such that the thermal distance between sensor **56** and the membrane comprises an air gap.

Flexible circuit **46** is connected to a printed circuit board (PCB) **48**. PCB **48** may be positioned within probe **26** or within handheld meter **32**. Flexible circuit **46** may provide electrical connections that connect the sensors to processing unit **36**, which may be mounted on PCB **48**.

A pressure sensor **50**, may also be mounted on PCB **48** and may be configured to sense the pressure applied between membrane **28** and the measurement site. Sensor **50** sends a pressure signal to processing unit **36**, which may indicate that an appropriate pressure is being applied by displaying a notification on screen **34** or by sounding an audible beep. A signal from sensor **50** to processing unit **36** may also be used to indicate that probe **26** is in place at the measurement site and that the temperature measurement process described hereinbelow may begin. Alternatively, a temperature change at sensor **54** may be used to initiate the temperature measurement process.

Pressure readings from pressure sensor **50** may also be provide a correction factor for the calculation of core body temperature, as described further hereinbelow.

PCB **48** also may comprise heating elements, such as resistors, not shown, that maintain a pre-determined initial temperature within the probe, such as 30° C.

When probe **26** is placed against the measurement site on the body of subject **24**, heat is conducted from the body through membrane **28** to sensors **54** and **56**. The rate of heat flux transferred to the probe is proportional to the difference between the thermal distances to sensors **54** and **56**.

Processing unit **36** performs the temperature measurement process by sampling temperature readings from each sensor at sample time intervals and calculating from these readings a core body temperature. In one embodiment, the sample time interval is 0.4 seconds. Using the heat flux algorithm described in the above-mentioned U.S. Pat. No. 6,280,397 (referred to hereinbelow as the '397 algorithm), the processing unit calculates from the temperature readings a local temperature. The local temperature, also referred to as a deep tissue temperature, reflects a temperature at a location under the skin that is the source of heat conducted to the sensors in the probe. The '397 algorithm is based on solving a heat conduction equation by utilizing multiple temperature readings, preferably, though not necessarily, from more than one sensor. Alternatively, other algorithms based on prediction and/or heat conduction may be used to determine the local temperature from sensor temperature readings.

The local temperature determined by the '397 algorithm is less affected than the surface temperature at the measurement site is to external factors such as ambient temperature and humidity. The local temperature is also less subject to variations in the body's heat regulation at the body's extremities. Consequently, there is a closer correlation between local temperature and core body temperature than there is between surface temperature and core body temperature.

In order to determine the core body temperature, processing unit **36** computes and applies an empirically-determined formula, which is described in detail in an Appendix hereinbelow. The formula is based on fitting a linear equation comprising several temperature-related parameters to clinically measured values of core body temperature. The temperature related parameters include sensor temperature readings, time-dependent temperature rates of change, and the value of local body temperature determined by the '397 algorithm. The formula is based on temperature readings made at a subject's forehead, using a two-sensor probe. Alternative empirical formulas may be derived for alternative measurement sites and for probes with one sensor, or for probes with three or more sensors. Empirical formulas may also be derived that account for variations in pressure as measured by pressure sensor **50**. When the probe is not firmly pressed against the measurement site, there will be a lower level of thermal contact, which increases the deviation between the temperature readings and the core body temperature. The deviation may be corrected by using measured pressure values in the empirical formula.

FIGS. **4**A-**4**E are schematic, side views of different configurations of temperature sensors within probe **26**, in accordance with an embodiment of the present invention. In all of FIGS. **4**A-**4**E, first sensor **54**, described above with respect to FIG. **3**, is mounted in direct thermal contact with membrane **28**. In alternative embodiments, not shown, first sensor **54** may also be separated from the membrane by a thermal distance.

The configuration of sensors in the embodiment of FIG. **4**A is essentially identical to the configuration of FIG. **3**. First sensor **54** and second sensor **56** are stacked, with a thermal insulating material **60** separating the two sensors. Insulating material **60** may comprise flexible circuit **46** described hereinabove. In an embodiment, insulating material **60** may comprise materials other than flexible circuit **46**, and electrical signal and power connections to the sensors may be provided by electrical means other than flexible circuit **46** (e.g., by electrical wires).

The embodiment of FIG. **4**B differs from that of FIG. **4**A in that the two sensors are not stacked. Rather, the thermal distance of sensor **56** is comprised solely of insulating material **60**, which separates second sensor **56** from membrane **28**.

The embodiment of the probe shown in FIG. **4**C comprises an additional, third sensor **62**, which is stacked above sensors **54** and **56**. Each sensor is separated from the sensor below by a layer of thermal insulating material **60**, such that the thermal distance of sensor **62** comprises sensors **54** and **56**, as well as two layers of insulating material. Both layers of insulating material may be printed circuit layers, or may be comprised of other heat insulating materials, which may be configured with differing thicknesses.

FIGS. **4**D and **4**E show additional configurations of the three sensors, **54**, **56**, and **60**, with and without some stacking. In the embodiment of FIG. **4**D, two of the sensors are stacked, while a third is not. In the embodiment of FIG. **4**E, none of the three sensors are stacked. It is to be understood that in additional embodiments, more sensors may also be configured in various locations with various stacking configurations, and with varying thermal distances. Furthermore, sensors configured in probe **26** may vary in their dimensions and sensitivities.

The data provided by additional sensors in embodiments configured with three or more sensors may be used to compute temperature with greater accuracy and/or speed than in embodiments that use only one or two sensors. In embodiments with additional sensors, processing unit **36** may use all or a subset of the sensors to determine the body temperature. For example, the processing unit may determine during the measurement process that certain sensors are not operating in their optimal ranges. Such sensors may include one that is configured for high thermal sensitivity and becomes saturated before an accurate temperature determination has been made, or a less sensitive sensor that detects only a negligible temperature change. Typically, thermal sensitivity a function of the structure of a sensor and its thermal distance to the measured heat source. Processing unit **36** may reject input from sensors operating outside of their optimal range. A determination of the core body temperature then is made using temperature readings from a subset of at least two sensors. The varying parameters of dimension, sensitivity, location, and thermal distance influence the optimal range of the sensors.

FIG. **5** is a schematic, side view of a temperature thermometer configured as a patch thermometer **68**, in accordance with an embodiment of the present invention. Patch thermometer **68** is configured to be affixed to the body surface, rather than to be held in the manner of thermometer **22**.

Patch thermometer **68** comprises a patch base **70**, which typically comprises a soft, durable material, such as is used for many types of medical patches. Patch thermometer **68** also comprises an adhesive material **76** so that the patch thermometer may be affixed to the skin. Alternatively, the patch thermometer may comprise a strap, not shown, that may encircle a part of the body, such as a limb, torso, or head, thereby binding the patch thermometer to the body. Patch thermometer **68**, like the handheld thermometer **22**, comprises probe **26** and membrane **28**. In this embodiment, probe **26** is mounted to patch base **70** by means of a compressible material **72** to further accommodate a contour of the body at the measurement site and to ensure that a consistent pressure is applied.

Patch thermometer **68** may also comprise additional elements similarly comprised in handheld thermometer **22**, such as screen **34**, shown in the figure, as well as a processing unit and a power supply, not shown in FIG. **5**. The screen may be used, together with a suitable pushbutton **78**, to display the time elapsed since the last dose of medication given to this patient and/or the time until the next dose should be administered, as described above, in order to assist the caregiver in administering the proper dosage at proper times.

Additionally or alternatively, patch thermometer **68** may comprise a wireless transmitter **80**, for transmitting temperature readings to a monitoring station or other receiver. The processing unit may thus be physically separated from the probe that is applied to the body.

After patch thermometer **68** is affixed or bound to the body, the temperature measurement process is essentially identical to the process described above with respect to the handheld thermometer.

Although the embodiments described above relate specifically to the measurement of temperature of a human body, the principles of the present invention may also be applied to other types of measurements, such as heat flux, and to other types of animate and inanimate bodies. Furthermore, although these embodiments make reference to certain types of fast, external measurement processes, the principles of the

present invention may likewise be applied in the context of other processes, such as continuous temperature monitoring.

It will thus be appreciated that embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

APPENDIX

U.S. Pat. No. 6,280,397, provides a method for rapidly determining a core body temperature based on heat flux through a thermometer when the thermometer is inserted into an orifice of the body. The accuracy of the derived temperature of U.S. Pat. No. 6,280,397 is diminished when temperature measurements are made at an external measurement site on the body.

In an embodiment of the present invention, an empirically-derived formula is used by the processing unit to determine core body temperature based on temperature readings made by sensors within the probe when the probe is applied to an external body surface. The algorithm uses temperature readings from two sensors: a first sensor positioned at a shorter thermal distance from the thermometer membrane, and a second sensor at a farther distance.

The empirically-derived formula for the core body temperature is given as a sum of factors, as follows (units are in degrees centigrade):

$$\text{Core Body Temperature}=C_5\cdot T_{b10\text{-}2}+C_{rdot5}\cdot T_{rdot5}+C_{bdot5}\cdot T_{bdot5}+C_{r10}\cdot T_{r10}+C_{b10}\cdot T_{b10}+C_3\cdot T_{avg}+C_4\cdot (T_{avg})^2+C_7\cdot (T_{avg})^3+C_6$$

In an exemplary embodiment, the constants used in the formula have the values shown in the following table:

C5	Crdot5	Cbdot5	Cr10	Cb10	C3	C4	C7	C6
0.2912	4.6451	−5.6806	−0.0891	0.4504	−3.5611	0.5801	−0.0264	41.08

The variables in the formula are given below. A typical interval between temperature readings is 0.4 seconds. (In alternative embodiments, a batch of temperature readings may be made a short intervals, such as 0.4 seconds, and averages of each batch may be used instead of individual readings.)

$T_{b10\text{-}2}$—The difference between the reading of the first sensor after 10 intervals and the first reading of the first sensor after 2 intervals.

T_{rdot5}—The rate of change of the temperature of the second sensor after 5 intervals (in degrees/sec).

T_{bdot5}—The rate of change of the temperature of the first sensor after 5 intervals (in degrees/sec).

T_{r10}—The reading of the second sensor after 10 intervals.

T_{b10}—The reading of the first sensor after 10 intervals.

T_{avg}—the heat-flux derived temperature of U.S. Pat. No. 6,280,397.

Alternative formulas based on the principles of the present invention will be apparent to those skilled in the art based on the above disclosure, and are considered to be within the scope of the present invention.

The invention claimed is:

1. A thermometric device, comprising:

a probe, comprising:

a membrane configured to be applied to an external surface of a body of a subject; and

one or more temperature sensors located within the probe in thermal contact with the membrane; and

a processing unit configured to receive a plurality of temperature readings from the one or more temperature sensors, to determine time-dependent parameters of temperature change responsively to the plurality of temperature readings, to calculate, a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors, and to calculate a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.

2. The device according to claim **1**, wherein the one or more temperature sensors comprise a plurality of temperature sensors at differing, respective thermal distances from the membrane, and wherein the processing unit is adapted to process the plurality of temperature readings responsively to the different thermal distances in order to calculate the core body temperature.

3. The device of claim **2**, wherein the plurality of temperature sensors comprises at least three temperature sensors, and wherein the processing unit is configured to select a subset of the temperature sensors and to determine the deep tissue temperature of the body responsively to the plurality of temperature readings provided by the subset.

4. The device of claim **2**, wherein a first of the plurality of temperature sensors has a first and a second of the plurality of temperature sensors has a second structure.

5. The device of claim **2**, and comprising an insulating material, which is interposed between at least one of the temperature sensors and the membrane in order to define the differing thermal distances.

6. The device of claim **5**, wherein the insulating material comprises a printed circuit.

7. The device of claim **2**, wherein the temperature sensors comprise a first temperature sensor in proximity to the membrane and a second temperature sensor stacked on the first temperature sensor so that a thermal distance of the second temperature sensor from the membrane comprises the first temperature sensor.

8. The device of claim **1**, wherein a contour of themembrane is configured so as to cause skin of the body to conform to the contour.

9. The device of claim **1**, wherein the device comprises a handheld meter, and wherein the probe is attached by a joint to the handheld meter.

10. The device of claim **9**, wherein the joint is flexible.

11. The device of claim **1**, wherein the probe and processing unit are physically separated.

12. The device of claim **11**, wherein the probe is compressible.

13. The device of claim 11, and comprising a wireless transmitter, for transmitting plurality of temperature readings from the probe to the processing unit.

14. The device of claim 1, and comprising a pressure sensor configured to indicate that an appropriate pressure is applied between the membrane and the external surface of the body.

15. The device of claim 1, and comprising a display, to display the core body temperature.

16. The device of claim 1, wherein the probe is configured to be affixed to the external surface of the body.

17. The device of claim 16, and comprising an adhesive material for affixing the device to the body.

18. The device of claim 1, and comprising a timer to measure intervals between administrations of a medication to the subject.

19. The device of claim 1, wherein the processor is operative to calculate the core body temperature responsively to sensing a change in a temperature reading from the one or more temperature sensors.

20. The device of claim 1, wherein the probe comprises a pressure sensor, which is adapted to measure a pressure of the probe against the body surface, and wherein the processing unit is operative to use the measured pressure in determining the core body temperature.

21. A method for thermometric measurement, comprising:

applying a probe, which comprises a heat-conducting membrane and one or more temperature sensors in thermal communication with the membrane, to an external surface of a body of a subject;

receiving a plurality of temperature readings from the one or more temperature sensors while the probe is applied to the surface of the body;

determining time-dependent parameters of temperature change responsively to the plurality of temperature readings;

calculating a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors; and

calculating a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.

22. The method of claim 21, wherein the one or more temperature sensors comprise a plurality of temperature sensors at differing, respective thermal distances from the membrane, and wherein calculating the deep tissue and core body temperatures comprises processing the plurality of temperature readings responsively to the different thermal distances in order to calculate the core body temperature.

23. The method of claim 22, wherein the plurality of temperature sensors comprises at least three temperature sensors, and wherein calculating the deep tissue temperature of the body comprises selecting a subset of the temperature sensors and calculating the deep tissue temperature responsively to the plurality of temperature readings provided by the subset.

24. The method of claim 22, wherein a first of the plurality of temperature sensors has a first structure and a second of the plurality of temperature sensors has a second structure.

25. The method of claim 22, and comprising interposing between at least one of the plurality of temperature sensors and the membrane an insulating material to define the differing thermal distances.

26. The method of claim 22, wherein the temperature sensors comprise a first temperature sensor in proximity to the membrane and a second temperature sensor stacked on the first temperature sensor so that a thermal distance of the second temperature sensor from the membrane comprises the first temperature sensor.

27. The method of claim 21, wherein a contour of the membrane is configured so as to cause skin of the body to conform to the contour.

28. The method of claim 21, wherein applying the probe comprises indicating that an appropriate pressure is applied between the membrane and the external surface of the body in order to receive the plurality of temperature readings.

29. The method of claim 21, wherein applying the probe comprises using an adhesive patch to affix the probe to the body.

30. The method of claim 29, and comprising transmitting the plurality of temperature readings from the probe to a telemetry receiver.

31. The method of claim 21, and comprising measuring intervals, using the probe, between administrations of a medication to the subject.

32. The method of claim 21, wherein calculating the core body temperature comprises determining the core body temperature responsively to sensing a change in a temperature reading from the one or more temperature sensors.

33. The method of claim 21, wherein calculating the core body temperature comprises determining the core body temperature responsively to sensing a pressure change on the membrane.

34. The method of claim 21, and comprising measuring a pressure of the probe against the body surface, wherein calculating the core body temperature comprises correcting for the difference between the core body temperature and the deep tissue temperature responsively to the measured pressure.

35. The method of claim 21, wherein calculating the deep tissue temperature comprises estimating the deep tissue temperature by solving a time dependent heat conduction transfer equation, and wherein correcting for the difference between the core body temperature and the deep tissue temperature comprises computing a polynomial function of the deep tissue temperature.

36. The device of claim 1 and wherein said processing unit employs a function comprising said time-dependent parameters for calculating said deep tissue temperature.

37. The method of claim 21 and wherein said calculating said deep tissue temperature comprises using a function comprising said time-dependent parameters.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,597,668 B2
APPLICATION NO. : 11/444710
DATED : October 6, 2009
INVENTOR(S) : Moshe Yarden

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

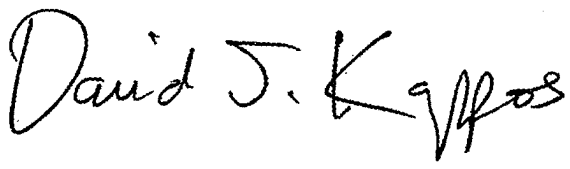
On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 146 days.

Signed and Sealed this

Twenty-eighth Day of September, 2010



David J. Kappos
Director of the United States Patent and Trademark Office

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MEDISIM LTD. V. BESTMED, LLC, 2013-1451

CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2013, true and correct copies of the foregoing PRINCIPAL BRIEF OF PLAINTIFF-APPELLANT MEDISIM LTD. and any supporting documents were caused to be served on the below listed counsel of record via electronic mail and ECF:

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MEDISIM LTD. V. BESTMED, LLC, 2013-1451

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or Federal Rule of Appellate Procedure 28.1(e) .

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   ☐ The brief uses a monospaced typeface and contains [*state the number of*] lines of text, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Appellate Procedure 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6).

   ☑ The brief has been prepared in a proportionally spaced typeface using **Microsoft Word 2010** in **Times New Roman, 14 pt.**, or

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Dated: October 15, 2013

/s/Scott S. Christie
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